(1)
Supreme Court, U.S.
FILED
97 1125 DEC 31 1997
OFFICE OF THE CLERK

No. _____

In The

Supreme Court of the United States

October Term, 1997

SURGIDEV CORPORATION,

Petitioner,

v.

KATHRYN NIEHOFF,

Respondent.

On Petition For Writ Of Certiorari To The Supreme Court Of Kentucky

PETITION FOR WRIT OF CERTIORARI

PHILIP W. COLLIER
Counsel of Record
W. KENNEDY SIMPSON
Of Counsel
STITES & HARBISON
400 West Market Street
Suite 1800
Louisville, Kentucky 40202-3352
(502) 587-3400
Counsel for Surgidev Corporation

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

184 pp

QUESTIONS PRESENTED

The Supreme Court of Kentucky interpreted the opinion in *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996), as precluding the defense of federal preemption in a state law product liability action against the manufacturer of an intraocular lens which was subject to an Investigational Device Exemption (IDE) by the Food & Drug Administration (FDA) in accordance with 21 U.S.C. § 360j(g).

The questions presented for review are:

1. Whether the express preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), preempts state common law product liability claims against the manufacturer of an investigational intraocular lens which is subject to device-specific IDE regulations, 21 C.F.R. Part 813, which relate exclusively to IOLs.

2. In the event that there is no express preemption, whether the comprehensive and rigorous IDE and IOL regulations create such a conflict with state law product liability claims, or so pervasively occupy the field, so as to impliedly preempt such claims.

LIST OF PARTIES AND RULE 29.1 STATEMENT

Petitioner Surgidev Corporation has no parent or subsidiary companies.

Respondent is Kathryn Niehoff.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
LIST OF PARTIES AND RULE 29.1 STATEMENT	ii
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	iv
PETITION FOR WRIT OF CERTIORARI	1
OPINIONS BELOW	1
JURISDICTION	1
CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED	1
STATEMENT OF THE CASE	2
1. INTRODUCTION	2
2. STATUTORY BACKGROUND	5
a. THE FDA DEVICE-SPECIFIC REGULATORY SCHEME FOR IOLS	5
b. THE MDA EXPRESS PREEMPTION PROVISION	11
3. PROCEEDINGS BELOW	11
REASONS FOR GRANTING THE WRIT	13
1. THERE IS A DIRECT CONFLICT BETWEEN STATE AND FEDERAL COURTS REGARDING IDE PREEMPTION	13
2. IDE PREEMPTION IS A FEDERAL ISSUE OF PARAMOUNT IMPORTANCE WHICH SHOULD BE RESOLVED BY THIS COURT	18
CONCLUSION	21

TABLE OF AUTHORITIES

Page

CASES

Baird v. American Medical Optics, 693 A.2d 904 (N.J. Super.), *cert. granted*, 700 A.2d 879 (N.J. 1997) 17

Becker v. Optical Radiation Corp., 66 F.3d 18 (2d Cir. 1995) 14

Berish v. Richards Medical, Inc., 937 F.Supp. 181 (N.D. N.Y. 1996) 17

Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) 16

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) 20

Chmielewski v. Stryker Sales Corp., 966 F.Supp. 839 (D. Minn. 1997) 17

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 19

Connelly v. Iolab Corp., 927 S.W.2d 848 (Mo. 1996), *cert. dismissed sub nom., Iolab v. Hunter*, 117 S.Ct. 2429 (1997) 17

Covey v. Surgidev Corp., 815 F.Supp. 1089, 1095 (N.D. Ohio 1993) 10, 14

Dmoch v. Iolab Corp., 610 N.Y.S.2d 28 (N.Y. App. Div. 1994) 14

Duncan v. Iolab Corp., 12 F.3d 194 (11th Cir. 1994) 14

Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) 19

Fry v. Allergan Medical Optics, 695 A.2d 511 (R.I.), *cert. denied*, 118 S.Ct. 374 (1997) 17

Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994) 14, 15

TABLE OF AUTHORITIES – Continued

Page

Gregg v. Kane, No. 95-4630, 1997 U.S. Dist. LEXIS 14269 (E.D. Pa. Sept. 5, 1997) 17

Hamilton v. Surgidev Corp., No. 92-3466, 1993 U.S. Dist. LEXIS 17858 (E.D. La. Dec. 9, 1993) 14

Hinners v. Optical Radiation Corp., 15 F.3d 1096 (11th Cir. 1994) 14

Hunsaker v. Surgidev Corp., 818 F. Supp. 744 (M.D. Pa. 1992), *aff'd*, 5 F.3d 1489 (3d Cir. 1993) 14

Kernats v. Smith Industries Medical Systems, Inc., 669 N.E.2d 1300 (Ill. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *pet. for cert. filed*, 65 U.S.L.W. 3632 (Mar. 4, 1997) 17

Lewis v. Intermedics Intraocular, Inc., 56 F.3d 703 (5th Cir. 1995) 14

Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997) 16, 18

Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996) ..... *passim*

Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997) 16

Petix v. Kabi Pharmacia Ophthalmics, Inc., 884 F. Supp. 92 (W.D. N.Y. 1995) 14

Powell v. Iolab Corp., No. CV 92-2432-SVW (JRX) (C.D. Cal. 1994), *appeal dismissed*, 1995 U.S. App. LEXIS 11908 (Fed. Cir. Apr. 27, 1995) 14

Shea v. Oscor Medical Corp., 950 F. Supp. 246 (N.D. Ill. 1996) 17

Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) 14, 15

TABLE OF AUTHORITIES – Continued

Page

Slingsby v. Optical Radiation Corp., No. 94-11801 EFH, Med. Devices Litig. Rptr. 16 (D. Mass. Mar. 6, 1995) 14

Wilson v. Bradlees of New England, Inc., 96 F.3d 552 (1st Cir. 1996), *cert. dismissed sub nom., Union Underwear Co. v. Wilson*, 117 S.Ct. 1083 (1997) 15

STATUTES

Med. Device Amendments to the Food, Drug & Cosmetic Act, 90 Stat. 34, codified at 21 U.S.C. §§ 301 et seq. 4, 5

21 U.S.C. § 360c(a)(1)(C) 5

21 U.S.C. § 360e(b)(1) 6

21 U.S.C. § 360e(b)(1)(B) 3

21 U.S.C. § 360e(d) 6

21 U.S.C. § 360j(g)(1) 2, 6, 20

21 U.S.C. § 360j(g)(2) 6

21 U.S.C. § 360k(a) 3, 11, 14

28 U.S.C. § 1257(a) 1

RULES AND REGULATIONS

21 C.F.R. § 50.20 9

21 C.F.R. § 808.1(b) 11

21 C.F.R. § 808.1(d) 11

21 C.F.R. Part 812 6

TABLE OF AUTHORITIES – Continued

Page

21 C.F.R § 812.1(a) 6
21 C.F.R. Part 813 ..... 3, 7
21 C.F.R. Part 813 Subpart D 9
21 C.F.R. Part 813 Subpart E 9
21 C.F.R. Part 813 Subparts C, G 10
21 C.F.R. § 813.1(b) 7
21 C.F.R. § 813.20 8
21 C.F.R. § 813.30 9
21 C.F.R. § 813.36 10
21 C.F.R. § 813.150 10
21 C.F.R. § 860.7 6
21 C.F.R. § 886.3600 11
42 Fed. Reg. 58875 (Nov. 11, 1977) 7
42 Fed. Reg. 58877 (Nov. 11, 1977) 7

ARTICLES AND MISCELLANEOUS

Armor Esteban & Shanna David, *"Medtronic": One Step Forward, Two Steps Back, 24 Prod. Safety & Liab. Rep. (BNA) 1054* (Nov. 8, 1996) 15

PETITION FOR WRIT OF CERTIORARI

Surgidev Corporation respectfully petitions for a Writ of Certiorari to review the judgment and opinion of the Supreme Court of Kentucky in this case.

OPINIONS BELOW

The opinion of the Supreme Court of Kentucky is reported at 950 S.W.2d 816 (Ky. 1997). App. 1a. The opinion of the Kentucky Court of Appeals is not reported. App. 45a. The trial court's opinions are not reported. App. 62a, 74a.

JURISDICTION

The judgment of the Supreme Court of Kentucky was issued on June 19, 1997. App. 1a. A petition for rehearing was denied on October 2, 1997. App. 44a. This Court's jurisdiction is invoked under 28 U.S.C. § 1257(a).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

The pertinent text of the following statutes and regulations are reprinted in the Appendix:

U.S. Const. art. VI
21 U.S.C. § 360e
21 U.S.C. § 360j
21 U.S.C. § 360k
21 C.F.R. § 808.1

21 C.F.R. § 812.1
21 C.F.R. Part 813
21 C.F.R. § 886.3600

STATEMENT OF THE CASE

1. INTRODUCTION

Innovative medical devices are vital to the public health and welfare. Most innovative medical devices are approved by the FDA only after the safety and efficacy of such devices have been established by valid scientific evidence based upon well-controlled clinical research in human subjects. Clinical trials of medical devices are performed pursuant to an Investigational Device Exemption (IDE). IDE devices are exempt from all statutory and regulatory requirements which apply to other medical devices, including safety and efficacy, manufacturing, labeling, and reporting. Instead, IDE devices are subject to comprehensive regulations governing all aspects of research and development, design, manufacture, labeling, reporting, and informed consent. The Congressional intent underlying the IDE system is to encourage "the discovery and development of useful devices . . . and to that end to maintain optimal freedom for scientific investigators in their pursuit of that purpose."[1] Because Congress had a particular interest in encouraging manufacturers of intraocular lenses (IOLs) to develop safety and efficacy data, the FDA also issued IDE

[1] 21 U.S.C. § 360j(g)(1).

regulations relating exclusively to IOLs.[2] The product in this case was a federally regulated Class III medical device which was subject to this comprehensive device-specific web of regulations.

In *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996), this Court considered the preemptive effect of 21 U.S.C. § 360k(a) in a case involving a medical device which was cleared for marketing as "substantially equivalent" to a device already on the market, commonly referred to as 510(k) premarket notification.[3] In a 4-1-4 decision, this Court found that state common law product liability claims against the manufacturer of a 510(k) device were not preempted. While a five-justice majority of the Court was of the opinion that the common law claims constituted "requirements" with respect to the medical device, a different five-justice majority appeared to rule that the 510(k) process lacked sufficient "device specificity" to constitute a federal "requirement applicable to the device" under 21 U.S.C. § 360k(a).

This case presents an issue which was not addressed in *Medtronic* – the applicability of the express preemption provision of the MDA to claims relating to an investigational IOL. The device in this case was not a 510(k) device, nor was it a device subject to the premarket approval (PMA) process characterized by this Court as "rigorous."[4] Instead, the product involved in this case was part of a clinical research investigation which was

---

[2] 21 C.F.R. Part 813.

[3] 21 U.S.C. § 360e(b)(1)(B).

[4] *Medtronic*, 116 S.Ct at 2247.

being carried out to determine whether the IOL was sufficiently safe and effective to be made available to the general public.

Relying exclusively on *Medtronic*, the Supreme Court of Kentucky, in a 4-3 opinion, departed from established federal precedent in ruling that state common law product liability claims against the manufacturer of an IDE IOL were not preempted by the Medical Device Amendments to the Food, Drug & Cosmetic Act (MDA). The majority erroneously concluded that there were no specific federal regulations applicable to the IOL which conflicted with Kentucky product liability claims, and erroneously concluded that state law claims cannot be preempted unless such claims were developed specifically with respect to medical devices. As pointed out by the dissent, exposing a manufacturer to tort liability after it has qualified for and is involved in a clinical investigation of a device is wholly inconsistent with the Congressional intent of encouraging discovery and development of innovative devices.

The Supreme Court of Kentucky's ruling is in direct conflict with a long line of federal appellate authority (six circuit courts) which began before *Medtronic*, and which has continued thereafter. In addition, IDE preemption is a federal issue of paramount importance in light of the express congressional intent underlying the IDE process and the device-specific investigational IOL regulations. Failure to resolve this conflict or address the issue will subject medical device manufacturers, as well as injured plaintiffs, to unpredictable and inconsistent results in each of the 50 states, and in corresponding federal jurisdictions.

2. STATUTORY BACKGROUND

a. THE FDA DEVICE-SPECIFIC REGULATORY SCHEME FOR IOLS

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Food, Drug & Cosmetic Act, 90 Stat. 534, codified at 21 U.S.C. §§ 301 et seq., to provide comprehensive regulation over all aspects of the medical device industry, from research and development to manufacturing and quality control to labeling and marketing. The MDA classified medical devices into three categories based upon potential risk to the public. Class III medical devices "present a potential unreasonable risk of illness or injury" and may not be marketed unless the manufacturer can prove "reasonable assurance" that the device is both safe and effective, a procedure known as premarket approval (PMA).[5] The PMA process is "rigorous", and manufacturers must submit detailed information to the FDA regarding the safety and efficacy of a device, which the FDA spends an average of 1,200 hours reviewing.[6]

It should be noted that there are two exceptions to the PMA procedure for Class III devices, neither of which applies to this petition. First, devices marketed before 1976 were "grandfathered" until such time as the FDA requires a PMA application. Second, in order to prevent manufacturers of grandfathered devices from gaining an unfair competitive advantage, devices which are "substantially similar" to Class III devices already on the market can be cleared for sale without going through the

---

[5] *See generally* 21 U.S.C. § 360c(a)(1)(C).

[6] *Medtronic*, 116 S.Ct. at 2247.

PMA process pursuant to a procedure known as 510(k) premarket notification.[7]

The most critical data upon which the FDA relies in determining whether a Class III device is safe and effective is derived from clinical investigations in human subjects. A PMA application cannot be approved unless there is "valid scientific evidence" based upon "well-controlled investigations" which province reasonable assurance of safety and efficacy.[8] These clinical investigations are conducted pursuant to an Investigational Device Exemption (IDE), which is a prerequisite for PMA approval. IDE devices are exempt from federal statutes and regulations relating to safety and efficacy, manufacturing, labeling and reporting.[9] The intent of Congress in enacting the IDE process was to encourage research and development of innovative medical devices:

> [T]o encourage, to the extent consistent with the protection of the public health and safety with ethical standards, the discovery and development of useful devices . . . and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.[10]

In response to the MDA, the FDA issued extensive regulations relating to IDEs for all medical devices.[11] In

---

[7] *See generally* 21 U.S.C. § 360e(b)(1).

[8] 21 U.S.C. § 360e(d); 21 C.F.R. § 860.7.

[9] 21 U.S.C. § 360j(g)(2); 21 C.F.R § 812.1(a).

[10] 21 U.S.C. § 360j(g)(1).

[11] *See generally* 21 C.F.R. Part 812.

addition, the FDA promulgated comprehensive IDE regulations relating specifically to IOLs.[12] The stated purpose of the IOL IDE regulations was to encourage research and development regarding safety and efficacy of IOLs.

> The Commissioner believes that restricting intraocular lenses to investigational use is appropriate to encourage intraocular lens manufacturers to develop safety and effectiveness data before the application of these premarket approval requirements.[13]

The FDA recognized that any use of IOLs involved safety and efficacy testing:

> Because the Commissioner believes that any implantations of an intraocular lens is a substantial risk procedure involving a critical investigational device whose safety and effectiveness has not been established, any use of the lens necessarily involves safety and effectiveness testing that is subject to the requirements of Part 813.[14]

Consistent with the IDE regulations relating to all medical devices, the FDA exempted IOL IDEs from federal statutory and regulatory requirements relating to safety and efficacy, manufacturing, labeling, and reporting.[15]

The IOL IDE regulations govern all aspects of the research and development, design, manufacture, labeling, reporting, and informed consent relating to IOLs. The

---

[12] 21 C.F.R. Part 813.

[13] 42 Fed. Reg. 58875 (Nov. 11, 1977).

[14] 42 Fed. Reg. 58877 (Nov. 11, 1977).

[15] 21 C.F.R. § 813.1(b).

sponsor/manufacturer begins the process by filing an IDE application which contains:

1. a statement of the intended use and method of administration of the IOL;
2. a complete description of the *design* of the IOL, including all components, ingredients, properties, and principles of operation;
3. a description of the manufacturing and quality control procedures for the IOL;
4. identification of the location of each investigational study and each institutional review committee;
5. a description of the investigational plan (protocol) for the study;
6. a statement that the investigational review committee has approved the investigational plan;
7. a copy of all informational material to be given to study subjects, including informed consent forms;
8. a copy of all device labeling; and
9. a copy of statements of all clinical investigators, including an agreement of each investigator to obtain written informed consent.[16]

The FDA can approve an IOL IDE only upon finding that:

1. there is reason to believe that the IOL is safe and effective for the purpose of the investigation;

---

[16] 21 C.F.R. § 813.20.

2. the IDE application does not contain any false statements or omit any information;
3. the investigational plan (protocol) is reasonable for scientific investigators to determine if the IOL is safe and effective;
4. the manufacturing and quality control procedures for the IOL assure adequate safety and effectiveness;
5. the proposed investigational study does not subject human subjects to undue risk; and
6. the benefits of the study outweigh the risks.[17]

Once an IOL IDE application has been granted, the investigational study is conducted by clinical investigators, ophthalmologists who are responsible for following the investigational plan, including obtaining written informed consent from all study subjects.[18] The study is reviewed and monitored by an independent committee of professionals and lay people known as an institutional review committee (IRB), which approves the investigational plan, approves each clinical investigator, assures sufficient record keeping, monitors study results, and assures that informed consent is obtained.[19] The sponsor/manufacturer has no direct contact with the patients, and is responsible for selection of clinical investigators, limiting distribution of IOLs to approved investigators, monitoring the progress of the study and evaluating data relating to safety and efficacy, keeping comprehensive

---

[17] 21 C.F.R. § 813.30.

[18] 21 C.F.R. Part 813 Subpart E; 21 C.F.R. § 50.20.

[19] 21 C.F.R. Part 813 Subpart D.

records, and providing progress reports and adverse reaction reports to the FDA.[20]

The FDA has the authority to conduct inspections of IOL manufacturing facilities and to review investigational study records at any time.[21] In addition, the FDA may withdraw an IOL IDE at any time upon a showing that:

1. the IOL may be unsafe or ineffective;
2. the investigational plan is not reasonable;
3. the study is not being conducted in accordance with the investigational plan;
4. the manufacturing and quality control procedures do not provide adequate assurance of safety and efficacy;
5. the study does not conform to FDA regulations; or
6. the investigational study subjects human subjects to undue risks.[22]

In the words of one court: "To say that the regulations concerning IOLs are expansive would be an understatement."[23]

---

[20] 21 C.F.R. Part 813 Subparts C, G.

[21] 21 C.F.R. § 813.150.

[22] 21 C.F.R. § 813.36.

[23] *Covey v. Surgidev Corp.*, 815 F. Supp. 1089, 1095 (N.D. Ohio 1993) (IDE IOL).

b. THE MDA EXPRESS PREEMPTION PROVISION

Section 521(a) of the MDA provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[24]

This express preemption provision was incorporated verbatim into FDA regulations relating to all medical devices.[25] That same regulation provides that state requirements are preempted only when the FDA has established "specific counterpart regulations . . . applicable to a particular device."[26]

3. PROCEEDINGS BELOW

The product involved in this petition is the Style 10 intraocular lens ("IOL") manufactured by Surgidev. An IOL is a Class III prescription medical device which is surgically implanted in patients with cataracts to replace the diseased natural lens of the eye.[27] The Style 10 lens was provided to

---

[24] 21 U.S.C. § 360k(a).

[25] 21 C.F.R. § 808.1(b).

[26] 21 C.F.R. § 808.1(d).

[27] 21 C.F.R. § 886.3600.

ophthalmologists who served as clinical investigators pursuant to an IDE which was granted by the FDA in April of 1978. Surgidev filed an application for premarket approval (PMA), which would have allowed full commercial distribution of the Style 10, in July of 1981. The application was referred to an expert advisory panel selected by the FDA, the Ophthalmic Device Panel, which recommended PMA approval of the Style 10 lens in November of 1982.

Respondent, whose vision had been significantly impaired by cataracts, had a cataract removed from her left eye by her ophthalmologist, Dr. John Hafner, in September, 1983. Dr. Hafner was an approved clinical investigator for the Style 10 lens, and had signed an agreement with Surgidev which required him to contain written informed consent from all Style 10 patients. The FDA had not acted on the PMA application of Surgidev by the time respondent's IOL was implanted, and in fact never acted on the application before May of 1988, when Surgidev voluntarily suspended the clinical investigation of the Style 10 lens with notice to all clinical investigators, including Dr. Hafner.

Respondent developed corneal decompensation, a known complication of cataract surgery with or without IOLs, in 1989, and the Style 10 lens was surgically removed in September of 1990. Unfortunately, respondent developed a surgical infection which resulted in the loss of her eye.

Respondent filed a civil action in the Jefferson Circuit Court in Jefferson County, Kentucky in August of 1991, alleging product liability claims of strict liability and negligence against Surgidev, and alleging medical negligence

claims against Dr. Hafner.[28] Surgidev moved for summary judgment on the grounds that the product liability claims were preempted by federal law. The motion was granted in part, and following limited discovery, summary judgment was granted on all remaining issues. App. 62a, 74a. On November 17, 1995, the Kentucky Court of Appeals affirmed the judgment in favor of Surgidev. App. 45a. The Supreme Court of Kentucky excepted discretionary review, and reversed the opinion of the Kentucky Court of Appeals and the judgment of the Jefferson Circuit Court in an opinion issued June 19, 1997. App. 1a. The petition for rehearing was denied by the Supreme Court of Kentucky on October 2, 1997. App. 44a.

REASONS FOR GRANTING THE WRIT

1. THERE IS A DIRECT CONFLICT BETWEEN STATE AND FEDERAL COURTS REGARDING IDE PREEMPTION.

The writ should be granted pursuant to Rule 10(b) of this Court, because a state court of last resort – the Supreme Court of Kentucky – has decided an important federal question in a way that conflicts with the decisions of United States Courts of Appeals – the Second, Third, Fifth, Sixth, Seventh, and Eleventh Circuits.

---

[28] Dr. Hafner was not a party to the appeal proceedings in Kentucky, and respondent's negligence claims against Dr. Hafner will proceed to trial following the resolution of this petition regardless of the result.

The issue of preemption with respect to IDE devices was first addressed in 1992 by the Seventh Circuit in *Slater v. Optical Radiation Corp.*[29] That Court, in a well-reasoned opinion involving an IDE IOL, found that state common law product liability claims were expressly preempted by the express preemption section of the MDA, § 521(a),[30] because such claims were different from, and in addition to, the federal requirements relating to IDE devices, including IOLs, and would necessarily frustrate the congressional goal of fostering scientific freedom and innovation.

The principles of *Slater* were followed by every federal appellate court which addressed the issue of IOL IDE preemption,[31] and with near unanimity by federal district courts and state courts.[32] This Court denied certiorari in

---

[29] 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992).

[30] 21 U.S.C. § 360k(a).

[31] *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Lewis v. Intermedics Intraocular, Inc.*, 56 F.3d 703 (5th Cir. 1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994); *Hinners v. Optical Radiation Corp.*, 15 F.3d 1096 (11th Cir. 1994); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994).

[32] *Petix v. Kabi Pharmacia Ophthalmics, Inc.*, 884 F. Supp. 92 (W.D. N.Y. 1995); *Slingsby v. Optical Radiation Corp.*, No. 94-11801 EFH, Med. Devices Litig. Rptr. 16 (D. Mass. Mar. 6, 1995); *Powell v. Iolab Corp.*, No. CV 92-2432-SVW (JRX) (C.D. Cal. 1994), *appeal dismissed*, 1995 U.S. App. LEXIS 11908 (Fed. Cir. Apr. 27, 1995); *Hamilton v. Surgidev Corp.*, No. 92-3466, 1993 U.S. Dist. LEXIS 17858 (E.D. La. Dec. 9, 1993); *Covey v. Surgidev Corp.*, 815 F. Supp. 1089 (N.D. Ohio 1993); *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Pa. 1992); *aff'd*, 5 F.3d 1489 (3d Cir. 1993); *Dmoch v. Iolab Corp.*, 610 N.Y.S.2d 28 (N.Y. App. Div. 1994).

two of those cases.[33] Thus, as of June 1996, there was national uniformity and predictability with respect to preemption of IDE product liability claims.

In *Medtronic v. Lohr*,[34] this Court addressed the effect of the express preemption provision of the MDA on claims relating to Class III 510(k) medical devices. In a 4-1-4 decision which has frustrated and befuddled judges and commentators alike,[35] the Court found that state product liability claims were not preempted. While a five-justice majority of the Court was of the opinion that the common law claims constituted "requirements" with respect to the medical device, a different five-justice majority appeared to rule that the 510(k) process lacked sufficient "device specificity" to constitute a federal "requirement applicable to the device" under the MDA. Significantly, this Court did not address the issue of preemption of IDE or PMA devices, nor did the opinion refer to *Slater* and its progeny.

In the wake of *Medtronic*, a direct conflict has arisen between federal courts and state courts regarding IDE preemption. Federal appellate courts have continued to

---

[33] *Slater, supra* note 29; *Gile, supra* note 31.

[34] 116 S.Ct. 2240 (1996).

[35] *See, e.g., Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552, 556 (1st Cir. 1996), *cert. dismissed sub nom., Union Underwear Co. v. Wilson*, 117 S.Ct. 1083 (1997) ("Not only is *Lohr* not conclusive on our own issue, but the divisions there make even more general forecasts shaky."); Armor Esteban & Shanna David, *"Medtronic": One Step Forward, Two Steps Back, 24 Prod. Safety & Liab. Rep. (BNA)* 1054 (Nov. 8, 1996) (describing *Medtronic* as "splintered decision of questionable scope" that "leaves the preemption doctrine largely unsettled.").

consistently hold that product liability claims involving IDE devices are preempted by the MDA.[36] For example, in *Martin v. Telectronics Pacing Systems, Inc.*, a case involving an IDE cardiac pacemaker, the Sixth Circuit, after attempting to analyze the multiplicity of opinions in *Medtronic*, concluded that the product liability claims constituted state law requirements which were preempted by the pervasive "device-specific" IDE regulations because such claims would "impede the implementation and enforcement of specific federal requirements."[37]

> The purpose of the exemption for investigational devices is to promote safety and innovation, the twin aims of the investigational device exemption of the MDA. To allow cause of action . . . under state law where the FDA has specifically exempted an investigational device from . . . regulations put forth the goal of the IDE exemption "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful medical devices intended for human use."[38]

---

[36] *Chambers v. Osteonics Corp.*, 109 F.3d 1243 (7th Cir. 1997); *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997). *But see Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) (no preemption of hip implant developed under IDE, classified as Class III, and reclassified as Class II). To the extent that *Oja* can be read to hold that the IDE process is not preemptive, there is an additional ground for granting the petition pursuant to Rule 10(a) of this Court – a conflict between federal courts of appeal.

[37] 105 F.3d at 1099.

[38] *Id.*

Federal district courts have disagreed, however, as to whether *Medtronic* preempts IDE claims.[39]

The decision of the Supreme Court of Kentucky in this case at bar, which held that state common law product liability claims were not preempted by the MDA, is in direct conflict with the decisions of the Second, Third, Sixth, Seventh and Eleventh Circuits.[40] The conflict does not end with this case, however, as there are additional decisions of state courts of last resort which directly conflict with the same federal appellate courts.[41] These decisions are in direct conflict with at least one state court of last resort, however. In *Fry v. Allergan Medical Optics*,[42] the Rhode Island Supreme Court ruled that the MDA preempted product liability claims involving an IDE IOL. Adding to the conflict, an intermediate state appellate court has found no preemption.[43]

---

[39] *Compare Chmielewski v. Stryker Sales Corp.*, 966 F. Supp. 839 (D. Minn. 1997) (IDE hip prothesis – preemption) and *Berish v. Richards Medical, Inc.*, 937 F. Supp. 181 (N.D. N.Y. 1996) (IDE IOL – preemption) *with Gregg v. Kane*, No. 95-4630, 1997 U.S. Dist. LEXIS 14269 (E.D. Pa. Sept. 5, 1997) (IDE laser – no preemption) and *Shea v. Oscor Medical Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996) (IDE cardiac defibrillator – no preemption).

[40] *Supra* notes 29, 31, 36.

[41] *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), *cert. dismissed sub nom., Iolab v. Hunter*, 117 S.Ct. 2429 (1997) (IDE IOL – no preemption); *Kernats v. Smith Industries Medical Systems, Inc.*, 669 N.E.2d 1300 (Ill. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *pet. for cert. filed*, 65 U.S.L.W. 3632 (Mar. 4, 1997). (IDE and PMA catheter – no preemption).

[42] 695 A.2d 511 (R.I.), *cert. denied*, 118 S.Ct. 374 (1997).

[43] *Baird v. American Medical Optics*, 693 A.2d 904 (N.J. Super.), *cert. granted*, 700 A.2d 879 (N.J. 1997) (IDE IOL – no preemption).

The conflict is particularly compelling in this case because the Sixth Circuit includes Kentucky. Consequently, product liability claims involving a specific IDE device will be preempted in a Kentucky federal court pursuant to *Martin*, but claims involving the same device will not be preempted in a Kentucky state court pursuant to *Niehoff*! The direct conflict should be resolved by this Court.

2. IDE PREEMPTION IS A FEDERAL ISSUE OF PARAMOUNT IMPORTANCE WHICH SHOULD BE RESOLVED BY THIS COURT

The writ should be granted pursuant to Rule 10(c) of this Court, because the petition involves an important question of federal law that has not been, but should be, settled by this Court.

Notwithstanding the direct conflict between the Supreme Court of Kentucky and six federal circuit courts, and corresponding conflicts between lower state and federal courts, the decision in the case at bar involves a significant federal question which should be settled by this Court. It is undisputed that the preemptive effect of the MDA on state law product liability claims involving IDE medical devices has not been addressed by this Court. There can be little doubt that the issue involves an important federal question given the congressional intent to encourage research and development of life-saving and life-preserving medical devices, as well as the importance of such devices to the public health and welfare.

There are a number of reasons why the issue should be settled by this Court. First and foremost, the fractured

decision in *Medtronic* raised many more questions than it resolved.[44] The plurality's hypothesis in Part V of the opinion that state law requirements must be "specifically developed with 'respect to' medical devices"[45] is remarkably inconsistent with the plurality opinion, authored by the same justice, in *Cipollone v. Liggett Group, Inc.*[46] which found that "general" common law product liability claims were preempted. While Justice Breyer joined in Part V of the *Medtronic* opinion, the focus of his occurrence was on the specificity of federal requirements, and did not address the issue of state requirements.[47] In addition, Justice Breyer's concurrence raised the issues of conflict and field preemption, which are principles of implied preemption.[48] This analysis further confused the seemingly inconsistent pronouncements of this Court regarding the relationship between express and implied preemption.[49] This Court should resolve whether implied preemption principles apply in cases where there is an express preemption statute. The pervasive scope of the IDE regulations certainly militate in favor of conflict or

---

[44] The dissent in *Medtronic* described the result as "bewildering and seemingly without guiding principle." 116 S.Ct. at 2262 (O'Connor, J.).

[45] 116 S.Ct. at 2258.

[46] 505 U.S. 504, 524-25 (1992).

[47] *Medtronic*, 116 S.Ct. at 2260-61 (Breyer, J.).

[48] *Id.* at 2261.

[49] *Compare Cipollone, supra* note 46 at 517 (express preemption provision precludes implied preemption analysis) *with Freightliner Corp. v. Myrick*, 514 U.S. 280, ___, 115 S.Ct. at 1488 (1995) (inference "at best" that express preemption clause forecloses implied preemption).

field preemption. Further, the *Medtronic* plurality failed to address the issue of *Chevron*[50] deference to agency interpretation of a preemption statute.

In addition to clarification of issues raised in *Medtronic*, there are significant public policy issues which underlay the petition for certiorari. This Court has recognized the "increasingly significant role in the protection of the health of our people" played by the Federal Government.[51] Likewise, this Court has taken note that over 1,100 Class III devices have been introduced since the enactment of the MDA in 1976.[52] Congress has decreed that development of new medical devices is of paramount importance to the public health and safety.[53] Subjecting medical device manufacturers to inconsistent liability exposure in each of the 50 states and corresponding federal districts can only have a chilling effect on "optimal freedom" of clinical research necessary to develop vital medical products. This is more than a mere possibility. In addition to the cases already decided after *Medtronic*,[54] this issue is presently pending before a multitude of state and federal courts. If preemption was of sufficient public importance for this Court to consider the 510(k) process in *Medtronic*, this case, where the federal regulations go to

---

[50] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

[51] *Medtronic*, 116 S.Ct. at 2246.

[52] *Id.* at 2247.

[53] 21 U.S.C. § 360j(g)(1).

[54] *Supra* notes 36, 39-43.

the heart of scientific research and development of medical devices, is of the highest degree of importance to federal law.

CONCLUSION

The Petition for Writ of Certiorari should be granted.

Respectfully submitted,

PHILIP W. COLLIER
Counsel of Record
W. KENNEDY SIMPSON
Of Counsel
STITES & HARBISON
400 West Market Street
Suite 1800
Louisville, Kentucky 40202-3352
(502) 587-3400
Counsel for Surgidev Corporation

December 31, 1997

TABLE OF CONTENTS

Page

Opinion of the Supreme Court of Kentucky reversing the decision of the Kentucky Court of Appeals and remanding for further proceedings in *Niehoff v. Surgidev Corporation* 1a

Order of the Supreme Court of Kentucky denying appellee Surgidev Corporation's petition for rehearing in *Niehoff v. Surgidev Corporation* 44a

Opinion of the Kentucky Court of Appeals affirming the trial court's grant of summary judgment on preemption grounds in *Niehoff v. Surgidev Corporation* 45a

Order of the Jefferson Circuit Court, Jefferson County, Kentucky, granting partial summary judgment to defendant Surgidev Corporation in *Niehoff v. Surgidev Corporation* 62a

Order of the Jefferson Circuit Court, Jefferson County, Kentucky, granting defendant Surgidev Corporation's motion for summary judgment in *Niehoff v. Surgidev Corporation* 74a

U.S.C. Const. art. VI 76a

21 U.S.C. §360e 77a

21 U.S.C. §360j 78a

21 U.S.C. §360k 83a

21 C.F.R. §808.1 ..... 85a

21 C.F.R. §812.1 ..... 90a

21 C.F.R. Part 813 ..... 91a

21 C.F.R. §886.3600 ..... 154a

RENDERED: JUNE 19, 1997
TO BE PUBLISHED

Supreme Court of Kentucky

96-SC-0127-DG

KATHRYN NIEHOFF — APPELLANT

ON REVIEW FROM COURT OF APPEALS
V. 94-CA-262-MR
JEFFERSON CIRCUIT COURT NO. 91-CI-05479
HON. EARL O'BANNON, JR., JUDGE

SURGIDEV CORPORATION, — APPELLEE

OPINION OF THE COURT
BY JUSTICE WINTERSHEIMER

REVERSING AND REMANDING

This appeal is from a decision of the Court of Appeals which affirmed a summary judgment by the circuit court determining that the claim for compensatory and punitive damages was properly dismissed because federal law preempted any claim for state tort relief.

The issue is whether the tort claim under Kentucky common law is in conflict with or divergence from any specific federal regulation applicable to the medical device which allegedly ultimately resulted in the loss of the patient's eye.

Facts of this Case

The product involved in this appeal is the Style 10 intraocular lens (IOL) manufactured by Surgidev. The

IOL is an artificial lens which replaces the natural crystalline lens in the human eye following cataract surgery. It is a prescription medical device which is surgically implanted in the patient's eye in order to replace the diseased natural lens of the eye. The Style 10 was a particular type of IOL known as a "closed-loop anterior chamber" IOL because it was specifically designed for implantation in the anterior chamber of the eye which is the space between the cornea and the iris. The Style 10 lens was provided to physicians who were ophthalmologists and served as clinical investigators pursuant to an investigational device exemption which was granted by the Federal Food and Drug Administration in April of 1978.

Niehoff, whose vision had been significantly impaired by cataracts, had a cataract removed from her left eye by her ophthalmologist, Dr. John Hafer, in September of 1983. Dr. Hafer used a surgical technique known as "extracapsular cataract extraction." The doctor was an approved clinical investigator for the Style 10 lens and had signed an agreement with Surgidev which required him to obtain written informed consent from all Style 10 patients. Niehoff claims she did not know at the time of her surgery that the Surgidev Style 10 was an investigational device which had not yet been approved by the FDA as safe and effective. Dr. Hafer had explained to her that there was some risk involved in the procedure, but he allegedly did not tell her that the lens was experimental or investigational. Federal law requires that manufacturers and physicians obtain informed consent from a patient regarding an implantation of an investigational IOL and have a signed form of informed consent. The

form explains specific complications of the procedure and advises the patient that her surgery will be part of a clinical investigation required by the FDA. There is no signed consent form in the record for the 1983 surgery. This Court recognizes that Dr. Hafer is not a party to this appeal and any claims against him will proceed following the resolution of this appeal regardless of the result.

Niehoff developed complications from the cataract surgery in 1989 and the Style 10 lens was surgically removed in September of 1990. She suffered a surgical infection which resulted in the ultimate loss of her eye. In 1991, she filed a civil action alleging product liability claims based on strict liability and negligence against Surgidev and alleging medical malpractice negligence against the physician in a separate suit. Surgidev obtained summary judgment on the grounds that the product liability claims were preempted by federal law. The Court of Appeals affirmed the reasoning that a court decision in a products liability or negligence suit may be established or define an acceptable standard and serve to compel a manufacturer to alter the design of a specific investigational device. It therefore imposes a different or additional requirement relative to the safety and effectiveness of the device, and consequently, the Court of Appeals concluded that it can be said to be of limited or specific applicability rather than of general applicability. Following the Court of Appeals decision, the United States Supreme Court rendered *Medtronic, Inc. v. Lohr,* 116 S.Ct. 2240 (1996), which held that state law claims for negligence and product liability are not automatically preempted. This Court accepted discretionary review.

We hold that the claims of Niehoff for negligence and product liability for the injury caused by this particular experimental medical device are not preempted in state court by federal law. Recovery under a Kentucky claim does not rest on a specific finding that any particular claim would conflict with the enforcement of any specific federal regulation. *Lohr, supra,* is not necessarily dispositive here. The congressional purpose behind the substantially equivalent rule discussed in Lohr is distinguishable from the research and development goal of the investigational device exemption. The FDA has a more specific regulation regarding IOLs. The result and rationale of Lohr is instructive in our disposing of this case.

The Federal Regulations

The purpose of Congress and the FDA in allowing the marketing of an investigational device did not imply any intention to insulate Surgidev from liability to a patient who had not assumed the risk. The reasoning of the Court of Appeals in transforming general products liability law into a requirement of limited or specific applicability, rather than general applicability, is unconvincing.

In 1976, Congress amended the Food, Drug and Cosmetic Act, 21 USCA §§301-393 (1982) so as to give the FDA regulatory authority over all medical devices. An IOL is a Class III device which means it potentially presents an unreasonable risk of injury to patients. Class III devices are ordinarily subject to a FDA pre-market approval process, including a determination that the

product is safe and effective, before marketing is permitted. However, in order to encourage research and development, Congress created an investigational device exemption under which the FDA may permit marketing for clinical investigation trial without pre-market approval.

21 U.S.C. §360k(a) provides that no state may establish with respect to a medical device any requirement which is different from or in addition to any applicable federal requirement. FDA regulations interpret the term "requirement," as used in the federal statute, as including state court decisions. A state requirement is preempted only when the FDA has established counterpart regulations or there are other specific requirements applicable to the particular device under the act. Moreover, according to the FDA, the act does not preempt state requirements of general applicability when the purpose of the requirement relates to other products in addition to devices. Examples of Class III devices are pacemakers, intrauterine devices, heart valves and IOLs.

The FDA had not acted on the PMA application of Surgidev at the time the IOL was implanted in Niehoff's eye. In addition, the FDA never acted on the application before May of 1988, when Surgidev voluntarily suspended the clinical investigation of Style 10 lenses with notice to all clinical investigative physicians.

Congress provided for the investigational device exemption as a means for collecting enough data to enable the FDA to make an informed decision on premarket approval. A review of the legislative history indicates that Congress did not believe the exemption was a

means for enabling a manufacturer to market an experimental device without a determination of its safety and effectiveness. The congressional act places no time limit on exemptions, however, the FDA expressed concern that investigational exemptions should not be used as a subterfuge for commercial distribution of lenses and that the investigational study should not be unduly prolonged. 42 Fed. Reg. at 58875. In the situation presented by this appeal, it appears that Surgidev sold the Style 10 lens as an investigational device for ten years without ever obtaining pre-market approval of the lens.

The FDA imposed narrow restrictions on the reach of §360k. In June of 1977, the agency announced that the regulation was intended to preempt only those state or local laws that directly and specifically relate to devices. 42 Fed. Reg. at 30383-84. The regulation subsequently promulgated by the FDA confirmed the narrow construction of §360k. In addition the agency also conditioned the use of the investigational exemption of any medical device upon the requirement of informed consent to be obtained from each human subject or a representative.

Surgidev argues that this case presents a purely legal question involving federal constitutional law and its application to state tort claims. They contend that every federal court which addressed the issue prior to *Lohr* found that state common law product liability claims involving IOLs were preempted. To support their argument they rely on *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), *cert. denied* 113 S.Ct. 327, which involved an investigational IOL with a design similar to that of the Style 10 IOL. The reasoning of *Slater, supra,* was adopted by every other federal appellate court which

considered the issue until the United States Supreme Court rendered *Lohr* in 1996, which involved a cardiac pacemaker, also a Class III medical device. The device in *Lohr* was never subjected to the PMA and IDA procedures but was authorized under 21 C.F.R. §510(k) substantial equivalents. The pacemaker in *Lohr* was not an investigational device and consequently the investigational device exemption would not apply in any event. Pre-market approval was postponed pursuant to §510(k).

The Kentucky Court of Appeals, in reaching its decision, agreed with the majority of federal circuit courts which have considered the question and based its decision on the *Slater* case. *Slater* completely barred a plaintiff from recovery under Illinois law for breach of warranty, strict liability and negligence in connection with a defective lens. The federal court conceded that the regulations imposed no requirement concerning the design of IOL devices and that there is no federal damage remedy that a plaintiff might invoke. The *Slater* court believed that the FDA had established procedures for determining whether the experimental design is safe and effective and these procedures sufficed as a counterpart regulation preempting any state law bearing on the safety of an IOL. All federal courts did not concur. In *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), the Ninth Circuit held that pre-market approval is supposed to benefit consumers and not insulate manufacturers from liability. *Kennedy* expressed concern over the disregard by other federal courts of the long-standing narrow construction of §360k by the Agency.

Medtronic, Inc. v. Lohr

In *Lohr*, the U.S. Supreme Court has now established that medical device amendments of 1976 do not preempt state law unless a specific state requirement contravenes a specific regulation. *Lohr* involved claims under Florida law against a manufacturer of a defective pacemaker. *Lohr* had sustained injury in 1990 when her pacemaker, a Class III device that Medtronic had placed on the market as the substantial equivalent device pursuant to 21 C.F.R. §510(k), failed because of a defective lead.

The opinion of the United States Supreme Court which was authored by Justice Stevens concluded that the medical devices amendments did not preempt any of the tort claims under the common law of Florida for negligence and strict liability. Our resolution of the Kentucky case is highly influenced by the decision of *Lohr* and the analysis we give it. Niehoff contends that *Lohr* provides a corrective and authoritative view that the real objective of Congress in 1976 was to provide consumer protection and informed deference to the FDA in resolving any difference between state and federal regulatory interest. Niehoff argues that *Lohr* effectively abolishes any immunity running to manufacturers under the medical device amendments. Surgidev, on the contrary, characterizes the *Lohr* decision as a 4-1-4 plurality asserting that the concurring opinion of Justice Breyer disagreed with the reasoning of the plurality but concurred in the result only. Part of our task is to sort out the varying views expressed by the members of the United States Supreme Court.

Our consideration of *Lohr* indicates that it is not necessarily dispositive of the situation presented in this case. However, we believe that *Lohr* is instructive and the

result and rationale of *Lohr* is of considerable assistance in reviewing the matter before us. In essence, *Lohr* held that the state tort claims for negligence and product liability were not always preempted. The Court noted that there is a presumption against preemption which occurs only when it is the clear and manifest intent of Congress as revealed by the language of the act and the purpose and structure of the statute as a whole. The *Lohr* decision permitted the plaintiff to maintain an action for the manufacturer's violation of FDA regulations. In that context, the state requirement is equivalent to and not different from the federal requirement. The decision also reasoned that the state common law requirements upon which the plaintiff based her claim were not specifically developed with respect to medical devices. The court stated that it was substantially informed by the FDA interpretive regulations in reaching that conclusion. The decision went on to say these state requirements therefore escape preemption because their generality leaves them outside the category of requirements that §360k envisioned to be with respect to specific devices such as pacemakers.

Surgidev also argues that *Lohr* supports a finding of preemption in this case because preemption is consistent with the express congressional intent. We disagree. The congressional purpose behind the substantially equivalent rule is distinguishable from the research and development ends of the investigational device exemption. The FDA has more specific regulations regarding IOLs. Congress and the FDA clearly intended to allow Surgidev to market its IOL as an investigational device, but this permission did not extend to an insulation of Surgidev from

any liability to a patient who had not assumed the risk. The distinctions in *Lohr* do not remove this case from its larger principles. There is a presumption against preemption and a deference to the FDA interpretation of preemption.

In our analysis of the decision rendered by the United States Supreme Court, we must examine the concurring opinion of Justice Breyer who joined with the author of the majority opinion, Justice Stevens, and three other justices for Parts I, II, III, VI and VII of the decision. Accordingly, these parts of the *Lohr* opinion constitute the majority view.

The doctrine of federal preemption is derived from the supremacy clause of the United States Constitution, Article VI. McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 4 L.Ed. 579 (1819), determined that a state law that conflicts with federal law is without effect. The historic police powers of the state are not preempted in the absence of "the clear and manifest purpose of Congress" to do so. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947). The United States Supreme Court has stated that it is reluctant to interpret a federal statute in such a way as to find preemption of subjects traditionally governed by state law. *CSX Transportation v. Easterwood*, 507 U.S. 658, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993). Determination of whether a federal statute preempts a state cause of action depends on the purpose of Congress in enacting the federal statute. *Malone v. White Motor Corp.*, 435 U.S. 497, 98 S.Ct. 1185, 55 L.Ed.2d 443 (1978).

The congressional purpose to preempt a state remedy may be determined in either of two ways. The first is whether the preemption is found in the express language of the statute, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). The second is to find preemption implied from the structure and purpose of the statute. Implied preemption occurs when the state law actually conflicts with federal law or where the federal law so thoroughly occupies the legislative field that it may be reasonably inferred that Congress left no room for the state to supplement it. Where a statute, such as the one we are considering, has a provision explicitly addressing preemption, that provision provides a reliable indicator of the congressional intent with respect to state authority. In *Cipollone*, the preemption statute in question provided that no requirement or prohibition based on smoking and health shall be imposed under state law with respect to advertising or promotion of any cigarettes.

Congress has given the FDA a unique role in determining the scope of §360k's preemptive effect. In most cases a state law will be preempted only to the extent that the FDA has promulgated a relevant federal requirement.

The *Lohr* decision reaffirms the concept that there is a presumption against the preemption of state regulations and recognizes the historic primacy of state regulation of matters of health and safety. The decision also recognizes that deference is due to the FDA's own interpretation of the medical device amendments, including §360k. The decision endorses the narrow interpretation of preemption and agrees that §360k does not preempt state or local requirements that are equal to or substantially identical to

requirements imposed by or under the federal act. The decision in *Lohr* clearly cautioned that future decisions on the scope of preemption under the federal act must focus on a comparison between specific federal and state regulations. Earlier decisions such as *Slater* had relied on the general FDA safety regulations to preempt any state common law theory challenging the design of a medical device, even though the federal regulations had not considered any specifics for the design of a particular device.

In reviewing the decision in *Lohr*, we are obliged to consider both the plurality analysis of Justice Stevens and the concurring opinion by Justice Breyer. The plurality opinion indicates that the term "requirements" has a narrower meaning in §360k than in the statute at issue in *Cipollone*. Justice Breyer disagrees with the plurality on two grounds. First, he believes that some common law actions are preempted by §360k, and second, he disagrees with the plurality dicta that preemption of common law claims would be few and rare. He establishes a standard of his own in which there must be a conflict with federal regulations and regulations must be so pervasive as to preempt the field of state common law actions. Justice O'Connor wrote a concurring opinion in which she disagreed with the analysis of the majority plurality and parts of the Breyer analysis. She did concur in finding that the common law defective design claims were not preempted. However, she believed that federal regulations relating to manufacturing and labeling were so comprehensive as to preempt common law claims based on negligent manufacturing or labeling. Three justices joined her opinion. Justice Breyer refrained from joining only Part IV, which contained a detailed distinction between

the previous analysis of preemption under a different statute regulating warnings on cigarettes and its analysis under the medical device amendments and Part VI, in which Justices Stevens, Kennedy, Souter and Ginsberg declined to resolve the contention by *Lohr* that common law duties are never requirements within the meaning of §360k and that the statute therefore never preempts common law actions. In his concurring opinion, Justice Breyer was explicit in providing his reasons for not joining IV and VI because he believed Part IV emphasized the difference between the medical device amendments and the preemption statute at issue in *Cipollone v. Liggett Group, Inc., supra,* because those differences are not relevant to this case. Justice Breyer did not join Part VI because he was not convinced that future incidents of medical device amendments preemption of common law claims will be few or rare.

We find the analysis by Justice Breyer to be critical to the decision of the U.S. Supreme Court and helpful in disposing of this case. His view was based on the proposition that §360k would not preempt a state court decision based on a finding by a jury under the common law, unless it directly contravened a specific federal regulation applicable to a specific device. Both Justice Stevens in his plurality and Justice Breyer determined that the courts must look to the FDA for responsibility in administering the medical devices amendments. Justice Breyer pointed out that the FDA had already promulgated a specific regulation designed to help. The regulation in question is 21 C.F.R. §808.1(d) which states in pertinent part that state requirements are preempted only when there are specific federal requirements applicable to a particular

device, thereby making any existing divergent state requirements applicable to the device different from or in addition to the specific federal requirements. Justice Breyer and the plurality opinion agreed that none of the state tort claims presented by *Lohr* were preempted.

The claims presented by Niehoff against Surgidev are similar to those presented by *Lohr* against Medtronic and are not precluded by the narrow specific approach to preemption referenced by the *Lohr* case.

The tort claims under Kentucky common law are not divergent from or in conflict with any specific FDA regulations applicable to the Style 10 IOL. Niehoff alleges that the Surgidev Style 10 was a defective and unreasonably dangerous product under Kentucky's common law strict liability. She further claims that Surgidev negligently designed, marketed and monitored the device and that her strict liability and negligence claims include allegations of failure to warn or to obtain her informed consent to the use of the experimental device.

The medical device amendments do not preempt her claim that Surgidev is strictly liable for the defective Style 10 IOL. Kentucky has adopted Section 402A of the *Restatement (Second) of Torts* which imposes strict liability on one who sells any product in a defective condition unreasonably dangerous to the user or consumer, even though the seller has exercised all possible care in the preparation and sale of the products. KRS 411.300 et seq. and *Dealers Transport Company v. Battery Distributing Company, Ky.*, 402 S.W.2d 441 (1966), in regard to the federal preemption concern, state that defective design and failure to warn are separate aspects of the same cause of

action, strict liability. *See Montgomery Elevator Co. v. McCullough, Ky.*, 676 S.W.2d 776 (1984).

Kentucky's strict liability case law and statutes are laws of general applicability to all products and fall beyond the scope of the federal preemption under §360k. The claim by Surgidev of preemption to the defective design allegation fails because there is no specific federal requirement which addresses or contradicts the specific opinions of her own expert which are in turn based upon a criticism of the Style 10 that appears in medical literature. There is no specific counterpart regulation that can preempt a Kentucky common law judgment based on a potential jury finding that the Style 10 IOL was defective or unreasonably dangerous because of its design. The claim by Niehoff that she never received any even basic instruction or warning as required by federal law is not in conflict with the applicable federal regulations. The federal amendments do not preempt her claim that Surgidev was negligent in its design, its failure to warn and its violation of federal regulations. A judgment by a Kentucky court or a potential jury verdict that Surgidev failed to use ordinary care in its design or in its failure to report its data to its investigators or any possible violation of federal regulations would not diverge from any specific federal regulation. Obviously, it would assist in enforcing them. The medical device amendments does not preempt state punitive damage remedies. There is no contradiction or conflict in any of these concepts should any of them become viable in a proper common law tort action in Kentucky.

Surgidev's many authorities presented to support its position are unpersuasive. We believe the citation by

Surgidev to the Federal District Court decision in *Berish v. Richards Medical Co.*, 937 F.Supp. 181 (N.D.N.Y. 1996), which was rendered after *Lohr*, is without merit. We are more persuaded by the decision of the Missouri Supreme Court in *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), which held that the medical device amendments did not preempt any of the state court claims of a plaintiff arising from the defective design of an IOL or the manufacturer's misconduct in failing to warn physicians of its high rate of complication. *See also Montoya v. Mentor Corp.*, 919 P.2d 410 (N.M. Ct. App. 1996).

Conclusion

It is the holding of this Court that the medical device amendments of 1976 do not preempt Kentucky law because there is no specific state requirement which contravenes, contradicts or conflicts with a specific federal regulation. The tort claims presented under Kentucky common law are not divergent from or in conflict with any specific federal regulation applicable to the Style 10 IOL.

The decision of the Court of Appeals is reversed and this matter is remanded to the circuit court for trial on the merits.

Graves, Lambert, Stumbo and Wintersheimer, JJ., concur. Special Justice Eric L. Ison dissents by separate

opinion in which Stephens, C.J., and Cooper, J., join. Johnston, J., not sitting.

ATTORNEY FOR APPELLANT:

Roy Kimberly Snell
P.O. Box 229, 115 West Main St.
LaGrange, KY 40031

ATTORNEYS FOR APPELLEES:

William Kennedy Simpson
Carol Dan Browning
Jeanne M. Picht
Stites and Harbison
400 West Market Street
Suite 1800
Louisville, KY 40202

RENDERED: JUNE 19, 1997
TO BE PUBLISHED

Supreme Court of Kentucky

96-SC-0127-DG

KATHRYN NIEHOFF — APPELLANT

ON REVIEW FROM COURT OF APPEALS
V. 94-CA-262-MR
JEFFERSON CIRCUIT COURT NO. 91-CI-05479
HON. EARL O'BANNON, JR., JUDGE

SURGIDEV CORPORATION, — APPELLEE

DISSENTING OPINION BY SPECIAL JUSTICE ERIC L. ISON

Congress' intent to preempt at least some state law is plain from the express language of 21 U.S.C. § 360k(a). The United States Supreme Court has made clear that some state common law damage claims are preempted by federal law. See, *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2615-2618 (1992). The first task before this Court is to decide whether Niehoff's state product liability claims are within the scope of those claims Congress intended to preempt. The second inquiry is whether claims for violation of federal regulations are properly before this Court, and if so treated, whether they also are preempted.

A state law claim is preempted if it conflicts with federal law or if federal law so thoroughly occupies the field as to make reasonable the inference that Congress left no room for state law to supplement it. See, *Cipollone*, 112 S.Ct. at 2617. This Court today concludes that Niehoff's product liability claims of strict liability and

negligence and her claims based on violation of federal regulations are not preempted. I believe that all of Niehoff's claims do conflict with federal law and that federal law thoroughly occupies the legislative field pertaining to the product of which Niehoff complains. I, therefore, respectfully dissent.

I.

The Intraocular lens ("IOL") at issue in this case is a Class III medical device, regulated by the Food and Drug Administration ("FDA") under the Medical Device Amendments of 1976 ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 360c et seq. Under the MDA, Congress provided that no state may establish any requirement which is different from, or in addition to, any requirement applicable to the IOL under the MDA, and which relates to the safety or effectiveness or any other matter included in the MDA which applies to the device. 21 U.S.C. § 360k(a). Pursuant to the MDA, the United States Congress has enacted numerous requirements which relate to the safety or effectiveness of Surgidev's IOL. The first such statute, essential to the resolution of this case is the Investigational Device Exemption ("IDE"). 21 U.S.C. § 360j(g).

Surgidev's IOL was marketed for human use from April 1978 to May 1988 under the auspices of an FDA clinical investigation. The requirements of this investigation are codified at 21 U.S.C. § 360j. This statute controlled the marketing and use of the device, and controlled the conditions under which the device reached Niehoff. Under Section (g) of that statute, Surgidev's IOL

was granted an exemption from having to meet several requirements under the FDCA.

> The [FDA] Secretary shall . . . by regulation prescribe procedures and conditions under which devices intended for human use may upon application, be granted an exemption from the requirements of Section 352, 360, 360d, 360e, 360f, 360i or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements **to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.**

21 U.S.C. § 360j(g)(2)(A) (emphasis added).

Moreover, under 21 U.S.C. § 360j(g), the Congress delegated authority to the FDA to require

> the establishment and maintenance of such records and the making of such reports . . . of data obtained as a result of the investigational use of the device during the exemption, as the [FDA] determines will enable [it] to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

21 U.S.C. § 360j(g)(2)(B)(ii).

Further federal requirements relating to the safety and effectiveness of Surgidev's IOL are codified in 21 C.F.R. § 813. These regulations contain extensive requirements which apply specifically and exclusively to IOL's such as the one at issue in this case. The regulations painstakingly detail the controls and standards an IOL must meet to qualify for the IDE. The IDE regulations

require a detailed application and plan for the clinical investigation, 21 C.F.R. §§ 813.20-813.25, and approval of the application by an institutional review committee in addition to the FDA. §§ 813.20, 813.30-813.42. These provisions further regulate virtually every aspect of the IOL's use during the investigation, from promotion and sale of the lens, committee monitoring of its performance, selecting investigators qualified to conduct the controlled investigation, outlining the parameters and protocol for that investigation, maintaining reports and records throughout the duration of the investigation, and ultimately the withdrawing of the exemption under certain conditions, §§ 813.65, 813.30(c)(5). Section 813.1(b) sets forth the general effect of the IOL exemption:

> (b) *Effect of exemption.* (1) In general, intraocular lenses are exempted from provisions of the following sections of the act and regulations thereunder when an application for exemption applicable to the lenses is in effect under this part: Misbranding under section 502, registration and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, records and reports under section 519, restricted devices under section 520(e), good manufacturing practices under section 520(f), and color additives under section 721.

During the ten year period when Surgidev's IOL was marketed under the IDE's provisions, there is nothing in the record to indicate that Surgidev had not satisfied the FDA in meeting the testing, record keeping, informed consent and other requirements of both the IDE statute and its copious accompanying regulations.

Now, however, Niehoff alleges that Surgidev's IOL was defective in that it was unreasonably dangerous for its intended use. She further alleges that Surgidev was negligent in the design, manufacture and sale of the IOL. In order to prevail at trial, Niehoff's claims require a fact finder to conclude that although Surgidev satisfied the requirements of 21 U.S.C. § 360j and 21 C.F.R. § 813, Surgidev sold the IOL in a defective condition that was unreasonably dangerous for human use. See *Dealers Transp. Co., Inc. v. Battery Distrib. Co., Inc.*, Ky., 402 S.W.2d 441, 446-447 (1965). Further, Niehoff asserts in her negligence claims that although Surgidev was permitted by the FDA's regulations to market the IOL as designed, manufactured, and labeled, it fell short of Kentucky's requirements to exercise the reasonable care required of an ordinarily prudent manufacturer. See, *C.D. Herme v. R.C. Tway Co., Inc.*, Ky., 294 S.W.2d 534, 537 (1956). Herein lies the actual conflict between Niehoff's state product liability claims and the federal requirements that controlled the investigational use of Surgidev's IOL. A comparison between the federal IDE and IOL requirements, and the elements of Niehoff's strict liability and negligence claims under Kentucky law, compels the conclusion that the state requirements Niehoff alleges fall squarely within the intended preemptive scope of the federal IDE statute and IOL regulations. Therefore, I cannot agree with the Majority's conclusion that Niehoff's state product liability claims of strict liability and negligence are not preempted.

II.

Before this Court reaches the conclusion from which I dissent, the Majority correctly states many principles of law with which I agree. As an initial proposition, I agree with the Majority's review of the seminal legal principles which guide the analysis in this case. The Majority ably describes the supremacy of federal law based on *McCulloch v. Maryland*, 17 U.S. (4 Wheat) 316 (1819) and the sovereignty of states where historic police powers are concerned. Further, I believe the Majority is correct in describing the settled methods of determining Congressional intent where state and federal law collide. In my view, the Majority's analysis breaks down when it comes to the weight it gives to the alleged failure to obtain informed consent for Niehoff's surgical procedure. The Court appears determined to provide a remedy for this apparent omission through the tort process, concluding

> [t]he purpose of Congress and the FDA in allowing the marketing of an investigational device did not imply any intention to insulate Surgidev from liability to a patient who had not assumed the risk.

As tempting as it is in deciding this case to follow the Majority in its concern that Niehoff may not have consented to the treatment at issue, this omission is not determinative of the preemption issue. If Niehoff did not give her informed consent, she is not without remedy, even if her claims before this Court, as pled, are preempted. Her action below against her approved investigational opthamologist remains. Surgidev, as the manufacturer of the IOL, was not required to obtain informed consent from patients who used its device. This

is true under tort law and under the protocol that controlled the clinical investigation in this case. To begin with, manufacturers such as Surgidev have no contact with patients. Surgidev was required under the federal regulations to obtain from each approved physician investigator, a written agreement to comply with the informed consent requirements of 21 C.F.R. § 50. There is no dispute that Surgidev complied with this regulatory duty by obtaining such a signed agreement from the physician who implanted the IOL in Niehoff's eye. Several cases addressing the issue spend little time in concluding that the duty to obtain informed consent lies with the physician and not the manufacturer. See, *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543 (3rd Cir.), *cert. denied* 115 S.Ct. 429 (1994); *Lewis v. Intermedics Intraocular, Inc.*, 56 F.3d 703, 707 (5th Cir. 1995): *Anderson v. George H. Lanier Memorial Hosp.*, 982 F.2d 1513, 1520 (11th Cir. 1993).

III.

I also respectfully disagree with the Majority's application of *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996) to this case. Again, I agree with the Majority that while the *Lohr* decision is not dispositive of this case, its analysis is instructive. I also agree, as discussed further below, that the method by which the pacemaker at issue in *Lohr* was authorized for sale in the marketplace is different from the method by which Surgidev's IOL was authorized for use. The Majority further provides an excellent analysis of the evolution in the law from *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th. Cir. 1992) and its progeny, to the Supreme Court's decision in *Lohr*.

The Majority, having observed that the "substantially equivalent" rule in *Lohr* is distinguishable from the research objectives of the IDE, and that the FDA regulations regarding IOL's are more specific, concludes that Lohr supports a finding that Niehoff's claims are not preempted. I do not agree with this conclusion.

My view of the difference between the Supreme Court's holding in *Lohr*, and the issue before this Court, comes in large part from the difference between the "substantially equivalent" approval process by which the pacemaker in *Lohr* reached the market, and the IDE approval process, by which Surgidev's IOL reached Niehoff here. The "substantially equivalent" requirement which controlled in *Lohr*

> [i]mposes a limited form of review on every manufacturer intending to market the new device by requiring it to submit a "pre-market notification" to the FDA. (The process is also known as a § 510(k) process). . . . If the FDA concludes on the basis of the § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis.

Lohr, 116 S.Ct. at 2246. As the Supreme Court observed, the "substantially equivalent" inquiry is brief and simple. It imposes no federal requirements on the design, manufacture or labeling of a product. *Lohr*, 116 S.Ct. at 2253-54. The "substantially equivalent" approval process

> is focused on equivalence, not safety. . . . [A]s a **result, substantial equivalent determination provide little protection to the public . . . "Substantially equivalent" devices never been**

> **formerly reviewed under the MDA for safety or efficiency**

Id. (emphasis added). In order not to be put at a competitive disadvantage, manufacturers such as the manufacturer in *Lohr* were allowed to freely market their devices because they were "substantially equivalent" to other grandfathered devices already on the market. Having been placed on the same playing field as their competitors, such manufacturers logically should also be subject to the same standard of liability. It follows that the Supreme Court in *Lohr* concluded that the "substantially equivalent" pre-notification process was not a federal requirement that preempted common law claims of negligence or strict liability. In contrast, the IDE process does review in great detail, devices approved under 21 U.S.C. § 360j for safety and efficiency. This distinction is critical because while the FDA has not examined or approved the safety and efficiency of "substantially equivalent" devices such as the pacemaker in *Lohr*, the FDA has clearly reviewed and approved the Surgidev IOL device marketed pursuant to the IDE as sufficiently safe and effective for investigative use on human beings.

Surgidev obtained approval to market its IOL under this exemption by submitting an application which included the following information:

> (2) A description of all components, ingredients and properties and a description of the principal of the operation of the device . . . in enough detail so that a scientist or a physician familiar with the general type of lens can make

> **a knowledge [sic] judgment about the anticipated safety and effectiveness of the lens in the proposed investigational study.**
>
> (3) A description of those methods, facilities, and controls used for the manufacture, processing, packing, and storage of the device in enough detail so that a person generally informed in that area **can make a knowledgeable judgment about the safety and effectiveness of the device in the proposed investigational study. . . .**
>
> (9) A copy of all informational material, including labels and other labeling, which is to be supplied to investigators as required by § 813.47(a).

21 C.F.R. § 813.20.

Surgidev was also required to submit an investigational plan which included,

> [t]he plan for obtaining informed consent from subjects and copies of all informational materials to be given to subject, including all forms and materials to be used in obtaining such consent. . . .

21 C.F.R. § 813.25.

Thus, when the FDA considered whether Surgidev's IOL could be used by investigators on patients including Niehoff, it first made a "knowledgeable judgment about the safety and effectiveness of the device." The FDA was also required to review and approve labeling and informed consent procedures applicable to the device

during the investigatory period. This is completely distinguishable from the perfunctory "substantially equivalent" approval by which the allegedly defective pacemaker reached consumers in *Lohr*.

The FDA was solely responsible for the review, approval and monitoring of Surgidev's application to include its IOL in the investigational study. Further, the FDA was solely responsible for the determination that Surgidev's IOL was exempt from the statute's good manufacturing principles, labeling and performance requirements. The FDA might have disapproved or withdrawn Surgidev's right to participate in the investigation under 21 C.F.R. § 813.30(c) if it made any of the following findings:

> (2) . . . . The report of prior investigation of the intraocular lens is inadequate to support a conclusion that it is reasonably safe to begin or continue the proposed investigational study.
>
> (3) **There is reason to believe that the lens may be unsafe or ineffective when used for the purpose or in the manner for which it is to be investigated. . . .**
>
> (4) The investigational plan described in the application is not a reasonable plan, in full or in part, for scientific investigation to determine whether the investigation device is safe or effective.
>
> (5) The methods, facilities, and controls used for the manufacturing, processing, packing, storage, or implantation of the lens **do not assure adequately the safety and effectiveness of the lens. . . .**

> **(8) The proposed investigational study subjects humans [sic] subjects to undue risks.**

Id. (emphasis added).

There is no evidence in this case that the FDA made any such finding. On the contrary, when the FDA approved Surgidev's IOL for marketing under the IDE, it concluded that Surgidev's IOL was safe and effective to be used for the purpose and manner for which it was to be investigated.[1] It further concluded that Surgidev's method for manufacturing and processing the lens assured adequately the safety and effectiveness of the device. Finally the FDA approved the proposed investigational study of the device finding it did not subject humans to undue risk. However misguided one may argue that these approvals may have been in retrospect, Niehoff may not be heard to collaterally attack the FDA's findings and attempt to reverse them in filing its state court action. Unlike the Petitioner's common law claims in *Lohr,* Niehoff's strict liability and negligence claims in this case collide directly with the federal requirements that applied to the subject device. Niehoff alleges requirements that are different than and in addition to the federal law which controlled the use of Surgidev's device and therefore her claims should be preempted.

---

[1] Certainly, Niehoff is correct that the FDA never approved Surgidev IOL as safe and effective for commercial distribution but this fact proves nothing in support of her claim. The entire purpose of the clinical investigation approved by the FDA was to determine the safety and effectiveness of the IOL *prior to* its approval for commercial distribution.

IV.

Congressional intent is the touchstone of all preemption analysis. See, *Lohr*, 116 S.Ct. at 2250, (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96 (1963)). Congress and the FDA intended to insulate manufacturers from liability to individuals asserting common law strict liability and negligence claims such as Niehoff's claims in this case because they interfere with and threaten the federal interest which is plain on the face of the statute:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use **and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.**

21 U.S.C. § 360j(g)(1) (emphasis added).

Exposing a manufacturer to tort liability after it has qualified for and is involved in a clinical investigation of its device, is wholly inconsistent with the objective of maintaining "optimum freedom for scientific investigators." That is why the FDA expressly exempts manufacturers from the pre-marketing approval process, and perhaps most importantly from general good manufacturing, labeling and performance standards under the MDA during the investigation of that device. The fact that Surgidev's IOL was exempt from following the good manufacturing practice requirements under the FDCA, as well as labeling or "misbranding" requirements, and performance standards under the statute is convincing evidence of Congress' intent to preempt state common law

actions against manufacturers based upon similar theories of liability. Notably, these federal requirements from which investigational devices are exempt, are also the standards the Supreme Court decided in Lohr were requirements of "general enforcement" with no preemptive effect in that case. *Lohr*, 116 S.Ct. at 2256. Logically then, if the Supreme Court found these general federal requirements were identical with the common law manufacturing and labeling claims in *Lohr*, they are similarly coincident to Niehoff's general common law claims in this case. Thus, the FDA's decision to exempt IDE devices from the general federal requirements for good manufacturing, performance and labeling, instructs that IDE devices are also exempt from state common law claims brought on the same grounds.

The Majority insists that Niehoff's claims are not preempted because they rest upon state laws of "general applicability." However, the Majority's conclusion is contravened by the Supreme Court's acknowledgment that there *are* general state laws which are preempted by conflicting federal requirements.

> [W]e do not believe that this statutory and regulatory language necessarily precludes general federal requirements from ever preempting state requirements, **or general state requirements from ever being preempted. . . .**

Lohr, 116 S.Ct. at 2257 (emphasis added, quotations omitted); see also *Chambers v. Osteonics*, No. 96-1742, 1997 U.S. App. LEXIS 6301 (7th Cir. Apr. 3, 1997).

The Court in *Lohr* could not ignore the "overarching" concern that only particular state requirements were preempted in that case, but even there, the Court acknowledged that general state requirements were subject to preemption where they threaten to interfere with a specific federal interest. *Id.* This is such a case. Here, not only do Niehoff's state law claims threaten the express federal interest in "maintaining optimum freedom for scientific investigators," but Niehoff's claims threaten the federal interest encouraging "the discovery and development of useful devices intended for human use." Niehoff's state law claims further threaten federal interest in exempting IDE devices from the general requirements of good manufacturing, misbranding, and performance. Niehoff's general state law claims threaten the federal interest in permitting the investigational use of devices to determine their safety and effectiveness. Finally, Niehoff's state law claims threaten the federal interest in "so thoroughly occupy[ing] a legislative field . . . as to make reasonable the inference that Congress left no room for the states to supplement it." *Cipollone,* 112 S.Ct. at 2617.

This is certainly an instance in which the legislative field has been thoroughly occupied by Congress. Here, Congress has authorized the FDA to exempt an IOL from its pre-market approval process, allowing the device to be implanted by a federally approved physician investigator, under the authority of a federally monitored clinical investigation, pursuant to the federal requirements contained in 21 U.S.C. § 360j and 21 C.F.R. § 813. Courts may infer Congress' intent to occupy a legislative field to the exclusion of state law "where the pervasiveness of the federal regulation precludes supplementation by the

State, where the federal interest in the field is sufficiently dominant, or where 'the object sought to be obtained by the federal law and the character of obligations imposed by it . . . reveal the same purpose.' " *Schneidewind v. ANR Pipeline Co.*, 108 S.Ct. 1145, 1150 (1988), (quoting *Rice v. Santa Fe Elevator Corp.*, 67 S.Ct. 1146, 1152 (1947)). The pervasiveness of the federal regulations pertaining to the IOL, as well as the dominant express federal interest in protecting scientific freedom in order to encourage the development of medically sound devices, confirms Congress' intent to occupy the legislative field. Thus, only to the extent that Niehoff's state law claims are consistent with or substantially identical to the copious federal regulations that govern investigational IOL's may they coexist with federal requirements in this field.

V.

As indicated by the Majority, the analysis by Justice Breyer in his concurring opinion is critical to the U.S. Supreme Court's decision in *Lohr*, and helpful in disposing of this case. Justice Breyer joined the plurality in Parts I, II, III, V and VII of the Court's Opinion. *Lohr*, 116 S.Ct. at 2261. I agree with the Majority's reiteration of Justice Breyer's reasons for not joining Parts IV and VI of the Majority Opinion. I further agree that Justice Breyer reads 21 C.F.R. § 808.1(d) to require specific federal requirements in order to displace divergent state requirements by preemption. However, I cannot find any support in Justice Breyer's Opinion that would lead to the Majority's conclusion that

> the claims presented by Niehoff against Surgidev are similar to those presented by Lohr against Medtronic and are not precluded by the narrow specific approach to preemption referenced by the *Lohr* case.

Justice Breyer's concurring opinion answered two questions. First, Justice Breyer agreed that the MDA's preemption of state requirements easily reached to preempt state tort actions for damages. Second, Justice Breyer answered the question of whether the MDA preempted the particular state tort claims at issue in that case. Justice Breyer's preemption analysis in *Lohr* focused primarily on the requisite degree of specificity of the *federal* requirement, not the *state* requirement raised by the Petitioner in that case. For example, Justice Breyer observed that federal administrative agencies have leeway to determine which regulations will have preemptive effect. 116 S.Ct. at 2260. Also, Justice Breyer looked at the methods federal agencies can use to communicate their preemptive intent. Notably, Justice Breyer's quote from the FDA's preemption regulation was edited to exclude all of the references that described the specificity required for a *state* statute to be preempted by that section. Instead, Justice Breyer focused on the fact that the *federal* regulations in *Lohr* were not specific enough to have the preemptive effect that the Respondent manufacturer in that case urged upon the court. Nonetheless, the Majority in this Court has read Justice Breyer's opinion to imply that a certain degree of specificity is required for *state* requirements to be preempted by the MDA. In my view, the Majority reads into Justice Breyer's words a view that is not expressed by his language, and it results in a

conclusion on the preemptive effect of the MDA which is incorrect in the instant case.

VI.

The conclusion that Niehoff's state common law product liability claims and negligence claims are preempted by the MDA, is supported by all the reported federal court decisions rendered since the Supreme Court's decision in *Lohr*.

The Majority dismisses the decision in *Berish v. Richards Medical Co.*, 937 F.Supp. 181 (N.D.N.Y. 1996) without discussion as being "without merit."[2] Although the device in *Berish* was an IDE hip implant, and not an IOL, the court found that the general IDE regulations (21 C.F.R. § 812) "largely mirror" the IDE regulations relating to IOLs (21 C.F.R. § 813). The court cited the case of *Becker*

---

[2] The majority states without elaboration that it is more persuaded by the Missouri Supreme Court's decision in *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo.1996). The Court in *Connelly* cites Part IV of the *Lohr* plurality's opinion, which was specifically disapproved by Justice Breyer, and it does so incorrectly. The Missouri Supreme Court incorrectly indicates that the *Lohr* plurality decided the § 360k exemption is ***"limited"*** to device specific enactments of positive law. In reality, the plurality in *Lohr* said that it read the language of § 360k to ***"suggest . . . that its focus*** is device specific enactments of positive law. . . . " The plurality also said that

> the legislative history also confirms our understanding that § 360k simply was not intended to preempt most, let alone all, general common-law duties enforced by damages actions.

Lohr, 116 S.Ct. at 252-53.

v. Optical Radiation Corp., 66 F.3d 18 (2nd Cir. 1995), for its holding that state tort claims involving an investigational closed loop anterior chamber IOL were preempted because the MDA and the IOL regulations specifically exempt experimental IOLs from the safety and effectiveness standards usually imposed on medical devices. Applying the same reasoning to the investigational hip implant, the *Berish* court held that plaintiff's claims for defective design, warning and testing were preempted. The *Berish* court further found that this result was consistent with *Medtronic*, stating:

> This Court reads nothing in *Lohr* that compels a different conclusion. Unlike the § 510(k) devices that so troubled the *Lohr* court, IDEs are subject to regulations that " . . . set forth detailed procedures for determining whether [IDEs] are safe and effective." *Id.* Moreover, IDEs are subject to specific regulations promulgated for application, not generally to all devices, but to IDEs specifically. Finally, Congress has expressly exempted IDEs from certain regulations, as set forth above. Based on the foregoing, the Court can see no reason to reconsider its findings that the plaintiff's state common law claims sounding in negligence and strict products liability are preempted.

Berish, 937 F.Supp. at 185.

The Majority did not discuss the Sixth Circuit case of *Martin v. Telectronics Pacing Sys., Inc.*, No. 94-4003, 1997 U.S. App. LEXIS 1627 (6th Cir. Jan. 31, 1997), applying Ohio law. On remand from the United States Supreme Court in light of the *Lohr* decision, the Sixth Circuit in

Martin held that all of Plaintiff's state common-law product liability claims against a pacemaker manufacturer were preempted. The *Martin* case contains an apt description of the distinction between the 20 hour process required to obtain "substantially equivalent" approval for devices to be marketed under the § 510(k) process, and the set of complex and comprehensive regulations which govern the IDE process. Declining the Plaintiff's invitation to re-characterize the approval process pertaining to the device at issue in *Martin*, the Court viewed the IDE process as dispositive in its determination that the Plaintiff's claims were preempted in that case. The Sixth Circuit's reasoning in *Martin* applies here.

The Majority also did not make reference to the Ninth Circuit's most recent post *Lohr* decision, *Papike v. Tambrands, Inc.*, No. 95-55173, 1997 U.S. App. LEXIS 2870 (9th Cir. Feb. 20, 1997). The *Papike* opinion is significant for at least three reasons. First, it sheds further light on the question of whether state laws of "general applicability" can be preempted by the MDA. The *Papike* Court acknowledges that § 360k preempts state common law requirements that are developed "with respect to" medical devices, and not those which merely describe a general duty. The plaintiff in *Papike* relies upon language from Part V of Lohr to argue that the generality of her tort claims leaves them outside the preemptive reach of § 360k. The Ninth Circuit Court explains, however, that

> [I]n Section V [of *Lohr*], the Court evaluates the specificity of the general state common-law requirements, **but only after concluding that the federal labeling and manufacturing requirements at issue were not specific to**

> **pacemakers.** . . . [I]t is clear enough that the Court found no preemption of the common-law claims largely because the pacemaker was not subject to any device-specific FDA regulations. In addition, Section V acknowledges that the statutory and regulatory preemption language does not necessarily preclude "general" statements from ever being preempted.

Papike, 1997 U.S. App. LEXIS 2870 at 13-14.

The same analysis applies to this case. The federal labeling and manufacturing requirements at issue in *Lohr* were not specific to the device whereas the federal requirements at issue in this case, as in *Papike*, are highly specific to the IOL device. This distinction places Niehoff's claims in that category of general state requirements which are well inside the category of preempted state requirements despite their apparent generality.

Papike is also significant because it is a Ninth Circuit case. After *Slater*, and before *Lohr*, when virtually every jurisdiction held state law claims were preempted, Niehoff points out in her Brief that the Ninth Circuit "buck[ed] the preemption tide" in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995). Now, in *Papike*, the Ninth Circuit is again among the first courts to analyze *Lohr*'s findings and holds that general state law claims, which actually conflict with specific and pervasive federal requirements, are preempted.

Finally, the *Papike* opinion is significant because it sheds significant light on Justice Breyer's separate opinion. Disposing of any remaining inclination to use Justice

Breyer's opinion as support for the view that state common-law actions of "general applicability" cannot be preempted, the *Papike* Court reasoned,

> it makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common-law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements. Instead, in *Medtronic*, Justice Breyer found "no actual conflict between any federal requirement and any of the liability-creating-premises of the Plaintiffs' state law tort suit. . . . " Here, there would be such a conflict.

Id. Here, as in *Papike*, there is conflict between specific federal requirements and the Appellant's state law tort suit.

In the most recently decided case of *Chambers v. Osteonics*, No. 96-1742, 1997 U.S. App. LEXIS 6301 (7th Cir., Apr. 3, 1997), the Seventh Circuit Court of Appeals held that

> claims for strict liability of breach of the implied warranty of merchantability "set up a direct collision with federal policy" because the FDA has already decided, rightly or wrongly, that a particular device can be sold, subject only a [sic] requirements, procedural in character and designed to assure that this experimental distribution was in fact a worthwhile experiment. Thus, these claims are preempted by the MDA because they impose requirements on Osteonics

> that are different from or greater than FDA requirements.

In so holding, the Court noted what many other courts have found that to allow state product liability claims would defeat the purpose of the investigational device exemption and impose liability on a manufacturer for an experimental device that meets all FDA standards and requirements.

Each of these post-*Lohr* decisions in my view persuasively support a conclusion that preemption of Niehoff's product liability claims is appropriate.

VII.

There remains the issue whether Niehoff has negligence claims alleging that Surgidev violated the federal statute and regulations controlling its device which survive preemption. If she does, those claims solely would escape preemption because

> [t]he regulations promulgated by the FDA expressly support the conclusion that § 360k does not preempt state or local requirements that are equal to or substantially identical to, requirements imposed by or under the act.

Lohr, 116 S.Ct. at 2255 (quotations omitted). In addressing this issue, two questions are presented: (1) whether such claims have been properly preserved for review by this Court, and (2) whether such claims, if properly preserved, would impose requirements different from and in addition to federal law.

First, Niehoff's Complaint in Jefferson Circuit Court does not allege that Surgidev violated any specific federal law, whether it be a claim involving failure to warn, labeling or informed consent. Despite the absence in her Complaint of any such allegations, Niehoff's claims of Surgidev's violation of federal regulations were addressed by the Jefferson Circuit Court in its Opinion granting Partial Summary Judgment to Surgidev. In this Opinion, the lower court dismissed Niehoff's strict liability claim, her claim for punitive damages, and some but not all negligence claims that contended Surgidev violated federal regulations. Limited discovery followed, after which the trial court granted Summary Judgment, dismissing all of Niehoff's claims.

Niehoff appealed to the Kentucky Court of Appeals. With respect to the claimed violations of FDA regulations, the one and only claim addressed by the Court of Appeals was Niehoff's claim "that Surgidev failed to warn its investigators . . . of data indicating that high complication rates accompanied the use of Style 10 lenses." The Court of Appeals held this claim to be preempted as it would "impose a separate and additional duty on manufacturers to notify investigators of any problems which accompany implantation."

Niehoff then filed a Petition for Discretionary Review before this Court. That Petition made no mention whatsoever to any alleged failure by Niehoff to comply with any federal regulations. It was on the basis of that Petition that this Court granted her Discretionary Review.

Surgidev asserts in its Brief that Niehoff's claims based on violation of the FDA regulations are not properly before this Court. Niehoff's Brief before this Court contains no statement with reference to the record showing whether the issue of Surgidev's violation of federal laws was properly preserved for review and, if so, in what manner as called for under CR 76.12(4)(c)(iv).

The fact that Niehoff's Complaint contained no allegations that Surgidev violated any federal regulations, that her Petition for Discretionary Review did not raise any such issue, and that the requirements of CR 76.12(4)(c)(iv) have not been followed, when taken together support the correctness of Surgidev's position that such claims are not properly before this Court. It is unnecessary, however, to reach or to decide this potentially fatal procedural deficiency because I agree with the Court of Appeals' decision that Niehoff's failure to warn claims seek to impose a separate and additional duty on manufacturers to notify investigators and that this duty would impermissibly add to the existing notification and recall requirements under the applicable federal law. The same rationale would apply to dispose of Niehoff's informed consent and other negligence claims based on violations of the FDA regulations as presented in Appellant's Brief. As such, Niehoff's negligence claims based on Surgidev's alleged failure to comply with federal regulations would also be preempted.

VIII.

Niehoff's state product liability and negligence claims would impose requirements on Surgidev that are

different from or in addition to the requirements imposed by the MDA and the accompanying FDA regulations. For the reasons discussed, I believe all of Niehoff's state law claims are preempted, and I would affirm the decision of the Court of Appeals.

Supreme Court of Kentucky

96-SC-0127-DG

KATHRYN NIEHOFF APPELLANT-RESPONDENT

ON REVIEW FROM COURT OF APPEALS

V. (94-CA-262)

APPEAL FROM JEFFERSON CIRCUIT COURT

(91-CI-05479)

SURGIDEV CORPORATION APPELLEE/PETITIONER

ORDER DENYING PETITION FOR REHEARING

The Petition for Rehearing by petitioner, Surgidev Corporation, is hereby **DENIED**.

Stephens, C.J., Cooper, Graves, Lambert, Stumbo, and Wintersheimer, JJ., concur.

Special Justice Ison voted to grant.

Johnstone, J., not sitting.

ENTERED: October 2, 1997.

/s/ Robert F. Stephens
Chief Justice

RENDERED: November 17, 1995; 10:00 a.m.
TO BE PUBLISHED

Commonwealth Of Kentucky

Court Of Appeals

NO. 94-CA-0262-MR

KATHRYN NIEHOFF — APPELLANT

V. APPEAL FROM JEFFERSON CIRCUIT COURT
HONORABLE EARL O'BANNON, JR., JUDGE
ACTION NO. 91-CI-05479

SURGIDEV CORPORATION — APPELLEE

OPINION
AFFIRMING

* * *

BEFORE: COMBS, EMBERTON, and JOHNSTONE, Judges.

COMBS, JUDGE. In this case of first impression, we are asked to determine whether the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §360c *et seq.*, 360k, to the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. §513 *et seq.*, 521(a), preempt Appellant's state tort law claims involving experimental medical devices. We hold that they do. We therefore affirm the trial court's entry of summary judgment in favor of Surgidev Corporation ("Surgidev").

I. FACTS

In September 1983, appellant Kathryn Niehoff underwent surgery to her left eye. The surgery was performed

by Niehoff's ophthalmologist, who removed a cataract and implanted an artificial intraocular lens, Style 10. The intraocular lens was manufactured, designed, and sold by appellee Surgidev.

In mid-1987, Niehoff began noticing decreased vision in her left eye. Ultimately, she was diagnosed with pseudophakic bullous keratopathy and was forced to undergo surgery to replace the intraocular lens. Following the surgery, she developed an infection which resulted in the loss of her left eye in September of 1990.

Niehoff instituted this action in the Jefferson Circuit Court in August of 1991. She alleged claims of negligence and strict product liability against Surgidev and medical negligence claims against her ophthalmologist.[1] Surgidev moved for summary judgment on the basis that the state law claims were preempted by federal law. The trial court granted the motion with respect to the strict liability claims and some of the negligence claims involving alleged violations by Surgidev of Federal Drug Administration ("FDA") regulations. Subsequent discovery revealed that there was no evidence to support the FDA regulation violation claims and the trial court also granted summary judgment on the remaining negligence claims. This appeal followed.

---

[1] Niehoff's ophthalmologist is not a party to this appeal. Claims asserted against him will proceed in the Jefferson Circuit Court notwithstanding disposition of this appeal.

II. SUMMARY JUDGMENT STANDARD

Summary judgment should not be granted unless the right to judgment is shown with such clarity that there is no room for controversy and it appears impossible for the nonmoving party to produce evidence at trial warranting judgment in his favor. *Steelvest Inc. v. Scansteel Service Center, Inc.*, Ky., 807 S.W.2d 476 (1991).

III. DISCUSSION

A. REGULATORY FRAMEWORK

The Medical Device Amendments give the FDA comprehensive regulatory authority over medical devices. The regulatory scheme provides that medical devices are to be classified into one of three broad categories with differing degrees of governmental regulation. 21 U.S.C. § 360c. The least regulated category consists of Class I devices. Class I devices are those that do not potentially present an unreasonable risk of illness or injury. 21 U.S.C.§ 360c(a)(1)(A). These devices are subject only to general controls – including good manufacturing practice requirements. 21 U.S.C. § 360j(f). Class II devices are those which cannot be classified as Class I devices because "the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness" of the devices. 21 U.S.C. § 360c(a)(1)(B). These devices are subject to special controls including performance standards, post-market surveillance, and patient registries. *Id.*

The most highly regulated group is the last. Class III devices are those which either are used to sustain human

life or health or potentially present an unreasonable risk of illness or injury to patients. 21 U.S.C. § 360c(a)(1)(C). These devices are subject to an extensive pre-market approval process. *Id.* This process may include the manufacturer's submission of safety and effectiveness data, protocols for tests and studies, and a list of product components. 21 C.F.R. § 814.20. Additionally, prior to approval, the manufacturer's application must undergo a formal review process by a selected panel of experts. 21 C.F.R. § 814; *See,* Susan M. Mesner, *Medical Device Technology: Does Federal Regulation of This New Frontier Preempt the Consumer's State Common Law Claims Arising From Injuries Related to Defective Medical Devices?*, 7 J.L. & Health 253 (1993).

In enacting the MDA, Congress was not only interested in protecting consumers, but it was also interested in encouraging research and development and in allowing new, beneficial medical devices to be marketed without delay. *Green v. Collagen Corp.*, 433 Pa.Super. 556, 641 A.2d 600 (1994), *citing King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993). To that end, Congress created an "investigational device exemption" (IDE), through which certain Class III medical devices could be specifically exempted from the rigorous pre-market approval process and other requirements.[2] 21 U.S.C. § 360j. "These Amendments

---

[2] Congress enacted the investigational device exemption (IDE):

> to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of

contemplated significant latitude would be given developers of IDE's in order 'to encourage innovation by exempting promising experimental devices from the usual requirement of establishing the safety and efficacy of a medical device before it can be sold. . . . ' " *Powers v. Optical Radiation Corp.*, 37 Cal.App.4th 1444, 44 Cal.Rptr.2d 485, 489 (1995), citing *Slater v. Optical Radiation Corp.*, 961 F.2d. 1330 (7th Cir. 1992), *cert. denied* (1992), ___ U.S. ___, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992); *see also* H.R.Rep.No 853, 94th Cong., 2d Sess. (1976), U.S.Code Cong. & Admin. News 1976, 1070. A manufacturer seeking an exemption for a particular medical device must apply to the FDA for permission to undertake clinical investigation trials. 21 U.S.C. § 360j(g)(2)(A).

In late 1977, the FDA issued 21 C.F.R. pt. 813, regulations pertaining specifically to investigational exemptions for intraocular lenses. These regulations require a detailed application describing the lens under investigation and setting forth a plan for studying its use in human subjects. 21 C.F.R. § 813.20. The manufacturer must assure that participating physicians will obtain informed consent from each patient equipped or treated with an IDE. 21 C.F.R. § 813.66(a)(6). The FDA may refuse an exemption if it finds that the investigational plan is not reasonable, that the lens is unsafe or ineffective, or that the manufacturing, processing or implantation methods and controls do not adequately assure the safety

---

useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators. . . .

21 U.S.C. §360j(g)(1).

and effectiveness of the device. 21 C.F.R. § 813.30(c). If an exemption is approved, an institutional review committee reviews and monitors all of the investigational studies. 21 C.F.R. § 813.60. "In sum, the [intraocular lens] Regulations broadly govern nearly all facets of the investigational program." *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir. 1994), *cert.denied*, ___ U.S. ___, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994); *See Covey v. Surgidev Corp.*, 815 F.Supp. 1089, 1095 (N.D. Ohio 1993) ("[t]o say that the regulations covering intraocular lenses are expansive would be an understatement").

At the time Surgidev's Style 10 intraocular lens was implanted in Niehoff's left eye, it was an experimental lens classified by federal regulations as an investigational medical device exempt from the pre-market approval process of the FDA. Niehoff was a participant in an FDA approved clinical investigation aimed at determining whether the lens was safe and effective.[3]

B. PREEMPTION

The doctrine of federal preemption is grounded in the Supremacy Clause of the Constitution, which dictates that federal law "shall be the supreme Law of the Land; and the judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl.2. State laws which conflict with federal laws and regulations are

---

[3] Niehoff asserts that she did not give her informed consent to become a participant in the clinical investigation. The effect of this allegation on the issue of preemption is discussed below.

therefore preempted – if Congress so intended. *Cipollone v. Liggett Group*, 505 U.S. 504, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992). Congress's intent to preempt state law may be explicit in the language of the statute; it may be implied by occupation of an entire field of regulation; or it may also be implied when there is a conflict between state and federal law. *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1111 (4th Cir.), *cert. denied*, 488 U.S. 908, 109 S.Ct. 260, 102 L.Ed.2d 248 (1988).[4] As the FDCA contains an express preemption clause, the main issue before this court is the interpretation of that provision.

In pertinent part, the preemption clause, §360k(a), provides as follows:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

This clause is interpreted by an FDA regulation which provides that the offending state "requirement" may be one "established by statute, ordinance, regulation, or

---

[4] "The existence of an express preemption clause supports an inference that Congress intended to limit the federal statute's preemptive scope to the express terms of the clause, although it does not mean that the express clause entirely forecloses any possibility of implied preemption." *Mitchell v. Collagen Corp.*, ___ F.3d ___, 1995 WL 576949 (7th Cir. 1995), (discussing *Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 1488, (1995).

court decision. . . . " 21 C.F.R. §808.1(b), (emphasis added). State or local requirements are preempted, however:

> only when the Food and Drug Administration has established *specific counterpart regulations* or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. §808.1(d), (emphasis added). The regulations also list a number of state "requirements" that are not preempted, such as those relating to warranties of fitness and unfair trade practices; state requirements that are equal or substantially identical to federal requirements; and state medical licensing requirements. *Id.*

C. GENERAL ALLEGATIONS

We first consider Niehoff's threshold arguments: (1) that the FDA has not created "specific counterpart" regulations; (2) that the regulations exempt her cause of action from the statute's preemption clause; and (3) that because Surgidev and her physician failed to comply with certain requirements, the lens was not properly the subject of an investigational device exemption. Each of these arguments is aimed at avoiding the preemptive effect of the statute.

Referring to 21 C.F.R. §808.1(d), cited above, Niehoff argues that a judgment based on Kentucky's negligence and strict products liability laws do not offend a "specific counterpart regulation" implemented by the FDA. This

argument was carefully addressed by Judge Posner in *Slater, supra,* holding that the FDA's regulations imposed no specific requirement with respect to the design of intraocular lenses, but concluding that:

> In the experimental phase the appropriate regulations of safety and effectiveness are procedural rather that substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect.

Slater, 961 F.2d at 1333. While Niehoff contends that the reasoning of *Slater* is erroneous, we are persuaded – as other courts examining the issue have been – that the analysis and conclusions comport with the intent of Congress in enacting the preemption provision. Thus, we conclude that a court decision affecting the design, safety or efficiency of an experimental medical device would, in fact, encroach upon specific procedural regulations implemented by the FDA and would, therefore, offend the federal preemption doctrine.

Next, Niehoff argues that Kentucky's negligence and strict products liability laws are laws "of general applicability" and that they consequently fall outside the limited scope of the MDA's preemption provision. Niehoff points to the language of 21 C.F.R. § 808.1(d)(1) in support of this contention. Also referred to in the discussion above, this interpretive regulation provides as follows:

> Section 521(a) does not preempt State or local requirements of general applicability where the

> purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R § 808.1(d)(1).

Niehoff argues that Kentucky's negligence and strict products liability laws are analogous to the UCC's "warranty of fitness" and, therefore, that they are requirements of "general applicability," escaping preemption by federal law. It is important to reiterate that Niehoff has not made a claim against Surgidev for the breach of any warranties. She is merely analogizing UCC claims and their continued viability under the preemption statute to her products liability and negligence claims. Close review of Niehoff's contention, however, reveals that the reasoning is flawed in many respects.[5]

Importantly, as was noted recently in *Mitchell v. Collagen Corp.*, ___ F.3d ___, 1995 WL 576949 (7th Cir. 1995):

> [T]he regulation does not speak to common law claims; its reference to requirements of "general applicability" is not to common law causes of action but to electrical codes and the U.C.C. – positive enactments of law. Indeed, section

---

[5] Some of the confusion may stem from the fact that the term "warranty of fitness" is ambiguous, failing to distinguish between the UCC's warranty of merchantability and its warranty of fitness for a particular purpose, and between express and implied warranties. 67A Am. Jur. 2d *Sales* § 746 (1985).

> 808.1(d) . . . is noticeably silent on the matter of state tort claims. . . .

Further, the causes of action asserted against Surgidev in this case, sounding in negligence and strict liability, are not analogous to claims based upon the UCC's "warranty of fitness." First, any express warranty of fitness as to an investigational device would be provided by the parties – not by the FDA or state law. *See Evraets v. Intermedics Intraocular, Inc.*, 29 Cal.App.4th 779, 34, Cal.Rptr.2d 852 (1994). Thus, "[w]hile the State provides for the enforcement of the parties' bargain, it does not define each party's duties." *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1325 (3rd Cir. 1995). The same cannot be said for state tort actions.

Second, the UCC provisions referred to in the regulation provide a remedy against any and all warranted yet defective products and is not a remedy or requirement directed at investigational devices alone. Thus, it can be said to be of "general applicability." A general requirement – applicable to any product and compelling merchants and manufacturers to abide by their warranties of fitness – is not preempted by federal law. On the other hand, *a court decision* in a products liability or negligence suit may establish or define an acceptable standard and serve to compel a manufacturer to alter the design of a specific investigational device pursuant to state statutory or common law. It therefore imposes a "different or addition[al]" requirement relative to the safety or effectiveness of the device that is the subject of the litigation. Thus, it can be said to be of *limited* or *specific* applicability rather than "general applicability." Litigation in this area clearly runs afoul of the preemption provision. *Contra*

Kennedy v. Collagen Corp., ___ F.3d ___, 1995 WL 606511 (9th Cir. 1995).

In a related argument, Niehoff maintains that there is no "principled distinction between permitting recovery under state law for an 'unfit' product and permitting recovery for an 'unreasonably dangerous product.' " One could hardly disagree with this statement. However, there is simply no support for Niehoff's assumption that recovery under state law against a manufacturer for an "unfit" product is permitted under the MDA. To the extent that recovery would be permitted under the Uniform Commercial Code as indicated by 21 C.F.R. § 808.1(d)(1), the action would be predicated upon a seller's breach of its express or implied warranties, not upon the manufacturer having produced an "unfit" device. *See Michael v. Shiley, Inc., supra*. Moreover, manufacturers of experimental devices are specifically precluded by regulation from making express warranties regarding their products.

With reference to these initial contentions, Niehoff argues last that she did not execute a consent form nor in any manner did she give informed consent to become part of the clinical investigation aimed at determining the safety and efficacy of Surgidev's Style 10 intraocular lens. Niehoff expressly denies that this failure to obtain her consent constitutes a separate cause of action against Surgidev. Instead, she argues that the exemption status of an investigational device is specifically conditioned upon a manufacturer's assurance that participants will give their informed consent; therefore, she contends that the MDA's preemption provision never became effective here. The failure to obtain consent may have constituted a

separate cause of action. However, the absence or existence of consent has no relevance to the fact of preemption as to the design of the investigational device itself.

A similar argument was addressed recently by the Second Circuit Court of Appeals. In *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2nd Cir. 1995), the court noted as follows:

> Becker argues that the Stableflex lens which was implanted in her eye was not "exempt" under the experimental device section of the MDA because Dr. Spalter failed to secure her informed consent before implanting the lens. . . .
>
> It may well be that the lens in question was not exempt from the general requirements of the MDA, but we find that whether the lens was exempt or not, Becker's state tort claims are preempted by the MDA.

The court concluded that the preemption clause was broad enough to encompass the state tort claims regardless of whether the lens manufacturer was entitled to an exemption for its experimental device. Relying on that analysis, we, too, conclude that whether or not informed consent was appropriately obtained is not determinative of the statute's preemptive effect. The argument must fail.

D. SPECIFIC ALLEGATIONS

Having examined the preemption provision of the MDA and the regulations interpreting it and having disposed of Niehoff's general allegations, we turn now to determine the effect of the preemption provision upon each of the specific claims asserted against Surgidev. *See*

Cipollone, supra (considering each of appellant's theories of recovery to determine if they were preempted). The question is whether Niehoff's claims give rise to state requirements that differ from or add to FDA requirements and relate to the safety or effectiveness of investigational intraocular lenses. If so, then the prosecution of the claims in Kentucky's court is preempted.

1. Negligence and Strict Liability

State tort claims involving Class III medical devices made available through an investigational device exemption have been litigated most frequently in the federal courts. Importantly, each federal court that has considered the issue of whether a manufacturer of intraocular lenses can be sued under state law theories of negligence or strict liability has concluded that such actions are expressly preempted by federal law. (*Lewis v. Intermedics Intraocular, Inc.*, 56 F.2d 703 (5th Cir. 1995); *Gile, supra; Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994); *Covey, supra; Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744 (M.D. Pa. 1992), *aff'd*, 5 F.3d 1489 (1993); *Slater v. Optical Radiation Corp., supra; Petix v. Kabi Pharmacia Opthalmics, Inc.*, 884 F.Supp 92 (W.D.N.Y. 1995).

The state courts of California have also recently considered the issue and have offered an in-depth analysis that we find persuasive. In concluding that a patient's negligence and strict liability claims against a lens manufacturer were preempted by the MDA, one court noted as follows:

State claims for negligence and strict liability undermine the congressional purpose of allowing lens manufacturers leeway in developing and perfecting their product. These theories are predicated on the notion that a manufacturer has a duty to market a safe product. By definition, experimental medical devices are not known to be safe products, yet society has an interest in encouraging their use, despite the risks involved:

> "[I]f experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer."

Evraets, supra at 787, citing, *Slater*, 961 F.2d 1330, 1334.

In her complaint, Niehoff alleged negligence and strict liability based upon the defective and unreasonably dangerous design, manufacture, and sale of the Surgidev, Style 10 intraocular lens. Despite overwhelming authority to the contrary, Niehoff contends that her negligence and strict products liability claims against Surgidev are not preempted. We disagree.

As Judge Posner noted in *Slater, supra*:

> The theory underlying the complaint is that the design of the [intraocular lens] was not sufficiently safe and effective to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided . . . that the [lens] could be sold, subject only to requirements, procedural in character . . . designed to assure that this experimental

> distribution was in fact a worthwhile experiment. The plaintiff wishes in the name of state tort law to impose additional requirements – namely that the [lens] have had design characteristics that it lacked – and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments.

961 F.2d at 1333. Niehoff's negligence and strict liability claims are, therefore, preempted. Summary judgment was appropriately entered.

2. Failure to Warn

Niehoff also claimed that Surgidev failed to warn its investigators – the ophthalmologists approved by the FDA to participate in the intraocular lens implantation – of data indicating that high complication rates accompanied the use of Style 10 lenses.[6] First, we note that the MDA does not include a private right of action. Thus, Niehoff is not afforded the right to enforce compliance with FDA regulations. To the extent, if any that her claim might survive this impediment, it survives only to fail immediately due to being preempted by federal law.

The MDA established a notification and recall requirement for unsafe medical devices. 21 U.S.C. § 360h requires the manufacturer to report to the FDA any problems with a device that causes serious harm or death. If the device is determined to present an unreasonable risk

---

[6] It should be noted that Niehoff's claim does not include an allegation that Surgidev fraudulently misrepresented facts or data to the FDA in order to obtain exempt status for the lens.

of substantial harm to the public health, then the FDA must notify all health-care professionals who use the device. *See* 21 U.S.C. § 360h(a). An exemption for an investigational lens may also be unilaterally withdrawn by the FDA if there is reason to believe that the lens may be unsafe. *See* 21 C.F.R. § 813.35(a). Niehoff proposes to impose a separate and additional duty on manufacturer's to notify investigators of any problems which accompany implantation. This duty would impermissibly add to the existing notification and recall requirements prescribed by federal law. It is, therefore, also preempted. *Hunsaker, supra.*

We hereby affirm entry of summary judgment by the trial court in favor of Surgidev on claims of negligence, strict liability, and failure to warn based upon the doctrine of federal preemption.

ALL CONCUR.

BRIEFS AND
ORAL ARGUMENT
FOR APPELLANT:

Roy Kimberly Snell
LaGrange, KY

BRIEF FOR APPELLEE:

W. Kennedy Simpson
Carol Dan Browning
Jeanne M. Picht
Louisville, KY

ORAL ARGUMENT
FOR APPELLEE:

W. Kennedy Simpson
Louisville, KY

NO. 91CI05479 JEFFERSON CIRCUIT COURT

DIVISION FIVE (5)

KATHRYN NIEHOFF PLAINTIFF

VS OPINION

SURGIDEV CORPORATION, ET AL DEFENDANTS

** ** ** **

The matters before the Court in this medical malpractice and product liability case are motions for summary judgment by the Defendants, John Hafner, M.D. ("Hafner") and Surgidev Corporation ("Surgidev"). The case, brought by the Plaintiff, Kathryn Niehoff ("Niehoff"), concerns an allegedly defective medical implant. Surgidev and Dr. Hafner contend that the statute of limitations operates as a complete bar. In addition, Surgidev contends, on its own, that federal law preempts, and consequently invalidates, any state law claims against it.

This case arose from events concerning the implantation of an experimental medical device in a patient's eye. The medical device is an intraocular lens, Style 10 ("lens"). The lens is a surgically implanted artificial one, which is implanted after a patient has cataract surgery. Surgidev manufactured the lens. Dr. Hafner, an ophthalmologist, surgically implanted one of the lenses in Niehoff's left eye, on September 7, 1983. Although the lens allowed Niehoff to see well at first, she began experiencing discomfort by 1987. The lens was removed on September 12, 1990 and she filed suit on August 27, 1991.

The following are Niehoff's statements concerning her knowledge of the alleged injury.

Niehoff: Well the best of my knowledge is that the implant that was put in my eye, it evidently started curling or doing something because it damaged the cornea of my eye. And for like three years my eye would water and feel like it was sand in it, and it would do that maybe two or three times a week sometimes, sometimes every day. Different times in three years it was constantly bothering me. . . .

Question: And you were complaining, started complaining to Dr. Hafner about it?

Niehoff: Right . . . He said eventually he's probably going to have to have that taken out.

Question: Why?

Niehoff: I guess he knew it was ruining my eye. He sent me to Dr. Newton to have her look at it. That was about three or four years before it had to be removed.

On the other hand, Niehoff contends that she did not have adequate knowledge, to start the running of the limitations period. When Dr. Hafner sent Niehoff to another physician, the other physician did not indicate that there was a special problem with this particular lens, according to Niehoff.

Question: And when you came back from seeing Dr. Newton it was your understanding that eventually that lens was going to have to come out because it was destroying your eye?

Niehoff: Well, he hadn't told me that. He just sent me there, he said my eye was getting worse and he wanted me to go to Dr. Newton to let her look at it.

Question: And then you came back from Dr. Newton and saw Dr. Hafner?

Niehoff: Right.

Question: And that was in '87?

Niehoff: Right.

Niehoff's statements concerning the lens may be based upon knowledge which she learned as a result of information she learned later, after removal of the lens.

> Question: It was your understanding that the lens warped in some fashion and came into contact with –
>
> Niehoff: Well, that's what Dr. Eiferman told me when he had taken it out. In fact, when he had taken it out the cornea had like leaned up – or the implant had leaned up against the cornea. And he had a terrible time taking it out, he said. And, in fact, he told me that the jelly in my eye, he had to push it back in order to get the implant out . . .

There is another possible date upon which the limitations period may have begun to run. Niehoff contends that Dr. Hafner failed to obtain her informed consent on this experimental procedure. Therefore, the other possible date is the date she allegedly learned she was the subject of an experiment. None of the parties have raised this, however.

The FDA approval for the lens was eventually withdrawn. Niehoff brings claims sounding in strict product liability and in negligence, against the lens manufacturer and the physician performing the surgery.

The Defendants contend that the limitations period has run. They argue that even with use of the discovery doctrine, Niehoff's claims are barred. The traditional test for application of the discovery doctrine is found in *Louisville Trust Co. v. Johns-Manville Products, Inc.*, Ky., 580 S.W.2d 497 (1979), which requires the defendant to show that the plaintiff discovered, or in the exercise of reasonable diligence should have discovered, not only that [she] has been injured but also that the injury may have been caused by the defendant's conduct. The limitations period begins to run on that date and not on the date the full extent of injury is known. *Farmers Bank & Trust Co. v. Rice*, Ky., 674 S.W.2d 510 (1984).

The Defendants contend that based upon Niehoff's statements concerning her discomfort with her left eye, that she had knowledge of her alleged injury. However, Niehoff contends that her injury arose from problems specific to the Style 10 lens. The distinction is whether she had knowledge only that her eye was rejecting the lens, or whether she had knowledge that something was wrong with the lens itself. It is interesting to note that the Defendants simultaneously are contending that the difficulties Niehoff experienced with her eye were not the result of the lens. (Surgidev Motion for Summary Judgment re: Statute of Limitations p. 6, note 3). This is the exact problem this Court has with the limitations argument.

Where the pertinent facts are not in dispute, the limitations issue can and should be determined by the Court. *Lynn Mining Co. v. Kelly*, Ky., 394 S.W.2d 755 (1965). However, in the face of conflicting evidence, the question of when the injury should have been discovered

is a question of fact. *Gill v. Warren*, Ky. App., 751 S.W.2d 33, 35 (1988); Kentucky Jurisprudence Sect. 15-14 Torts p. 122 (1987). As there are factual matters in dispute concerning Niehoff's knowledge of her eye problems, this issue is not one which may be decided as a matter of law.

The other matter which Surgidev, although not Dr. Hafner, brings, is whether Niehoff's claims are all preempted by federal law. Where federal law conflicts with state law, federal law prevails. *Wisconsin Public Intervenor v. Mortier*, 111 S.Ct. 2476 (1991). The federal law in question here is a provision of the Medical Device Amendment Act. This act governs the manufacture and sale of medical devices for human use. Within the act is a special exemption for medical devices classified as investigational devices. 21 U.S.C. Sect. 360 (j)(g). At the time of the implantation of Niehoff's lens, the lens was classified as an investigational device. 42 Fed. Reg. 58874 (Nov. 11, 1977).

The exemption prohibits a state from establishing any requirement concerning a device intended for human use:

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> 21 U.S.C. 360 k(a).

Surgidev contends that, as a result of the above-cited provision, any state law claim is preempted. Surgidev

contends that the state claims are impliedly, expressly, and actually preempted.

Preemption may be implied, express, or actual. Congress' intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). In the absence of an express congressional command, state law is preempted if that law actually conflicts with federal law. *Pacific Gas & Electric Co. v. Energy Resources Conservation and Development Commission*, 461 U.S. 190, 204 (1983). In addition, state law preempts federal law if federal law so thoroughly occupies a legislative field " 'as to make reasonable the inference that Congress left no room for the States to supplement it.' " *Fidelity Federal Savings & Loan Assn. v. De la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

However, there is no need to imply Congressional intent to preempt state law, where legislation expressly addresses the issue. *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608 (1992). In this case, the statute in question defines its preemptive reach. Consequently, the Court will first examine the issue expressly, from the context of the statute.

Niehoff brings various negligence and strict liability claims in the development, design, warning, and failure to obtain informed consent. The touchstone to preemption analysis is Congress' stated purpose. *Cippollone v. Liggett Group, Inc.*, 112 S.Ct. 2608 (1992). The stated purpose of the Medical Device Act is to "encourage, to the extent consistent with the protection of the public health

. . . the development of devices . . . " 21 U.S.C. Sect. 360(j)(g)(1). As the Congressional intent is stated, this Court does not need a divining rod to recognize that Congress did not intend to completely insulate manufacturers from liability when they negligently fail to meet federal statutory and regulatory law.

The stated purpose is also consistent with 21 C.F.R. 50.20. The regulation prevents the patient from making a binding written release which would waive the manufacturer's liability for all negligence. *Id.* Niehoff cites to a minority position, *Mitchell v. Iolab*, 700 F.Supp. 877 (E.D.La. 1988), which came to the same conclusion, reasoning that the federal regulation is consistent with Congress' intent and that state tort law is neither " . . . different from, or in addition to, any requirement applicable under this Act to the device . . . which relates to the safety and effectiveness of the device . . . " *Id.* citing 21 U.S.C. 360k(a).

Finally, the stated purpose is consistent with 21 C.F.R. Sect. 808.1(d), which states "State or local requirements of general applicability [are not preempted] where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (warranty of fitness))."

Niehoff contends that the strict liability and negligence law should be included as a law of "general applicability," and thus fall outside the scope of the preemption provision. Since the stated purpose is consistent with the regulation, it appears that the negligence and strict

liability claims are not expressly nor impliedly preempted.

Surgidev contends that strict liability and negligence claims are not laws of "general applicability," because they would impose specific additional requirements on the manufacturer. Surgidev cites to *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), in support of its argument that federal law preempts state claims. In *Slater*, another intraocular lens case, the Court excluded all state claims, reasoning that if there were a known safe and effective design, the device would no longer be experimental. *Id.* at 1333. The court did not embark upon the implied/express/actual analysis, but simply listed specific exceptions which other courts had found. For that reason, this Court finds *Slater* distinguishable. The list of exceptions were matters which were not actually preempted by the federal law.

In this case, certain state law issues, as in *Slater*, are actually preempted. The FDA made the determination that the lens was sufficiently safe for the experimental purposes and that Surgidev had gathered sufficient information to make the determination. Consequently, the Court will examine Niehoff's various claims in light of what would actually be preempted by the federal law and corresponding FDA determination.

STRICT PRODUCT LIABILITY-DESIGN DEFECT

The strict liability claims are in actual conflict with the federal law. Investigational devices are those which present a "potential unreasonable risk of illness or injury" so that extensive regulation is required to ensure

reasonably safe use. 21 U.S.C. sect. 360c(a)(1)(C). The FDA held hearings and evaluated the safety and effectiveness of the lens. Consequently, the FDA approval system for investigational devices is intended to ensure a reasonable level of safety for the lens. A strict liability claim requires that the plaintiff show the product was "defective," or "unsafe" for the purposes for which it was intended. In short, a Court determination on the strict liability claim would directly oppose the FDA determination that the product was sufficiently safe for investigational purposes. Therefore, the strict liability claim is preempted by the federal law.

NEGLIGENCE

Niehoff alleges negligence in the development, design, warning, and failure to obtain informed consent. Some of these claims do not actually conflict with the federal law. Niehoff contends that Surgidev violated a host of federal regulatory provisions. If true, such regulatory violations would be actionable as negligence claims. *Britton v. Wooten*, Ky., 817 S.W.2d 443 (1991); *see also* 57A AmJur Sects. 730 & 736 Negligence pp. 659-60, 663-65. The Court will address the similar claims together.

Niehoff claims negligence in the design and development of the lens. Moreover, the claim for negligence in the development and design would conflict with the FDA's determination that the lens was sufficiently safe, and is preempted.

Niehoff also claims that Surgidev negligently failed to provide sufficient information to the FDA. Specifically, Niehoff contends that Surgidev failed to ensure adequate

monitoring, particularly in light of the fact that a financially interested physician was the investigator for the manufacturer "sponsor." However, the FDA had approved the investigator when it approved the Investigational Device Exemption. Additionally, the FDA determined that Surgidev had provided sufficient information to make its determination. (FDA Ophthalmic Section Meeting notes, November 16, 1982; Defendant's Reply Memorandum, Exhibit C). Thus, this negligence claim conflicts with the FDA determination, and is preempted.

If Niehoff's claim is that Surgidev knew of problems, but withheld them, then that would be a matter of fraud. However, fraud must be specifically pleaded, and must be proved with clear and convincing evidence. At present, Niehoff has not alleged fraud. So, the Court will not address this avenue.

Niehoff contends that Surgidev negligently failed to warn physicians concerning problems with the lens, contrary to FDA recommendation, and negligently failed to warn physicians even after a report in 1985 called for a recall. The manufacturer "sponsor" shall supply all labelling requirements. 21 C.F.R. Sect. 813.47(a). Additionally, the sponsor shall notify each clinical investigator of the discontinuance of an investigational study. 21 C.F.R. Sect. 813.47(b). Niehoff contends that Surgidev failed to follow the labelling requirements and failed to notify the Dr. Hafner, the clinical investigator, of the discontinuance of the investigational study. Consequently, this negligence claim would not actually conflict with federal law, as it is based upon the federal regulations. Thus it is not preempted.

Niehoff further contends that Surgidev negligently failed to obtain here informed consent. The clinical investigator is the party with the duty to obtain the informed consent. 21 C.F.R. However, the sponsor shall assure that the controls for ensuring the device will be tested under conditions that adequately assure the safety and effectiveness in the study. 21 C.F.R. Sect. 813.45(c). As Surgidev had a duty under the federal regulations to assure that adequate controls were in place, a negligence claim for breach of that duty would also not be preempted by the federal law.

Under the federal scheme, the remedy from defective products or negligence is that the FDA may withdraw premarket approval. The plaintiff has no remedy under the federal scheme. The Court recognizes that it has the benefit of hindsight, in that the lens was withdrawn. However, this Court is allowing Niehoff to bring state tort claims based upon Surgidev's alleged failure to follow the federal regulations. Although the FDA determined that the lens was sufficiently safe and effective, the manufacturer-sponsor is not relieved of its duty to use reasonable care in following the federal regulations, to assure the safety and effectiveness of the study. "State or local requirements that are equal to, or substantially identical to," requirements under the Medical Device Act are not preempted. 21 C.F.R. Sect. 808.1(d).

Finally, Niehoff contends that she should be entitled to punitive damages. Recovery of punitive damages requires the plaintiff to prove, "by clear and convincing evidence, that the defendant from whom such damages are sought acted toward the plaintiff with oppression, fraud or malice." KRS 411.184(2). Since the Court has

limited the claims in this case to two claims for negligence, Niehoff will not be able to prevail on her punitive damages claim, as a matter of law.

ORDER

ACCORDINGLY, IT IS HEREBY ORDERED that the motion for summary judgment by the Defendant, Surgidev is GRANTED in part, and DENIED in part, consistent with this opinion, and the motion for summary judgment by the Defendant, John Hafner, M.D., is, respectfully, DENIED.

/s/ Earl O'Bannon
EARL O'BANNON, JUDGE
July 1, 1993

cc: Roy Kimberly Snell
P. O. Box 229
115 West Main Street
LaGrange, Kentucky 40031

Thomas C. Smith
502 Greenup Street
P. O. Box 353
Covington, Kentucky 41012-0352

W. Kennedy Simpson
1800 Capital Holding Center
400 West Market Street
Louisville, Kentucky 40202

William O. Guethlein
2300 One Riverfront Plaza
Louisville, Kentucky 40202

B. Frank Radmacher, III
300 West Liberty Street
Louisville, Kentucky 40202

NO. 91-CI-05479 JEFFERSON CIRCUIT COURT
DIVISION FIVE (5)

KATHRYN NIEHOFF PLAINTIFF

v. ORDER

SURGIDEV CORPORATION AND
JOHN N. HAFNER, M.D. DEFENDANTS

* * *

Defendant, Surgidev Corporation, having moved, and the Court being otherwise sufficiently advised:

IT IS HEREBY ORDERED AND ADJUDGED that the motion of defendant Surgidev Corporation, for summary judgment be and it is hereby granted, and any and all claims in this action against defendant Surgidev Corporation, be and they hereby are dismissed with prejudice at plaintiff's cost.

This is a final order, the Court having determined that there is no just cause for delay.

/s/ Earl O'Bannon
JUDGE, JEFFERSON
CIRCUIT COURT

Date: _____

Tendered by:

/s/ W. Kennedy Simpson
W. Kennedy Simpson
STITES & HARBISON
1800 Capital Holding Center
400 West Market Street
Louisville, Kentucky 40202-3352
(502) 587-3400
CO-COUNSEL FOR DEFENDANT
SURGIDEV CORPORATION

Thomas C. Smith
SMITH, WOLNITZEK, SCHACHTER &
ROWEKAMP
250 Grandview Drive
Suite 500
Ft. Mitchell KY 41017
(502) 578-4444
CO-COUNSEL FOR DEFENDANT
SURGIDEV CORPORATION

U.S. Const.

ARTICLE VI

All Debts contracted and Engagements entered into, before the Adoption of this Constitution, shall be as valid against the United States under this Constitution, as under the Confederation.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Senators and Representatives before mentioned, and the Members of the several State Legislatures, and all executive and judicial Officers, both of the United States and of the several States, shall be bound by Oath or Affirmation, to support this Constitution; but no religious Test shall ever be required as a Qualification to any Office or public Trust under the United States.

21 U.S.C. § 360e

§ 360e. Premarket approval

(a) General requirement

A class III device –

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(b) Regulation to require premarket approval

(1) In the case of a class III device which –

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

* * *

21 U.S.C. § 360j

§ 360j. General provisions respecting control of devices intended for human use

(a) **General rule.** Any requirement authorized by or under section 501, 502, 510, or 519 [21 USCS §§ 351, 352, 360, 360i] applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 [21 USCS §§ 360c, 360d, 360e] or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 [21 USCS §§ 351, 352, 360, 360i] which is inconsistent with a requirement imposed on such device under section 514 or 515 [21 USCS §§ 360d, 360e] or under subsection (g) of this section shall not apply to such device.

* * *

(g) **Exemption for devices for investigational use.** (1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section [enacted May 28, 1976], by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 706 [21 USCS §§ 352, 360, 360d,

360e, 360f, 360i, 376] or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted

in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (1)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption –

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing –

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if –

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph

(2), for an exemption for a device (other than an exemption from section 516 [21 USCS § 360g]) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

* * *

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) **General rule.** Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

(b) **Exempt requirements.** Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

(June 25, 1938, ch. 675, § 521, as added May 28, 1976, P. L. 94-295, § 2, 90 Stat. 574.)

21 C.F.R. § 808.1

§ 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to

the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in

addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing

requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed

under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption. In accordance with the procedures provided by this part.

21 C.F.R. § 812.1

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the act and regulations issued thereunder: Misbranding under section 502, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) (unless the sponsor states an intention to comply with these requirements under § 812. 20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 706.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

PART 813 – INVESTIGATIONAL EXEMPTIONS FOR INTRAOCULAR LENSES

Subpart A – General Provisions

Sec.
813.1 Scope.

813.2 Applicability.

813.3 Definitions.

813.5 General qualifications for an exemption.

813.10 Petitions for waiver of requirements.

813.12 Information previously submitted.

813.19 Requirements applicable to importers and exporters of intraocular lenses.

Subpart B – Applications for Exemption for Investigational Studies Involving Human Subjects

813.20 Application.

813.25 Investigational plan.

813.27 Report of prior experiences with the lens.

813.30 Food and Drug Administration review of and action on an application.

813.36 Withdrawal of an exemption.

813.38 Confidentiality of data and information in an application.

813.39 Supplemental applications and submissions concerning applications.

Subpart C – Sponsor Responsibilities in Investigational Studies of Intraocular Lenses

Sec.

813.40 General.

813.42 Review of the investigational study by FDA and the institutional review committee.

813.43 Selection of investigators.

813.45 Control over the intraocular lens.

813.46 Monitoring the investigational study.

813.47 Submitting information to investigators.

813.50 Promotion and sale of intraocular lenses.

Subpart D – Institutional Review Committee

813.60 Requirement of institutional review committee.

813.63 Membership of an institutional review committee.

813.65 Procedures for review and monitoring of investigational studies by an institutional review committee.

813.66 Procedures and criteria for review of investigational studies by an institutional review committee.

813.70 Review by institution.

813.79 Actions when review by an institutional review committee is inadequate.

Subpart E – Investigator Responsibilities in Investigational Studies of Intraocular Lenses

Sec.

813.100 General.

813.101 Review of investigational study by FDA.

813.103 Review of investigational study by institutional review committee.

813.105 Conformity to investigational plan.

813.107 Control over intraocular lenses.

813.119 Disqualification of a clinical investigator.

Subpart F – Informed Consent of Human Subjects

813.120 General requirements of informed consent.

813.130 Elements of informed consent in agreement.

Subpart G – Inspections, Reports, and Records

813.150 Inspections.

813.153 Reports.

813.155 Records.

Subpart H – Investigational Studies That Do Not Involve Human Subjects

813.160 Conditions of exemption.

813.170 Termination of exemption.

AUTHORITY: Secs. 301, 501, 502, 520, 701, 704, 801, 52 Stat. 1042-1043 as amended, 1048-1051 as amended, 1055, 90 Stat. 547, 568-571, 576-578 (21 U.S.C. 331, 351, 352, 360j, 371, 374, 381).

Subpart A – General Provisions

§ 813.1 Scope.

(a) *General.* This part provides that intraocular lenses may be exempted from any of the requirements of the act enumerated in paragraph (b) of this section that would otherwise be applicable to the device, to permit investigational studies of the device by experts who are qualified by scientific training and experience to investigate the safety and effectiveness of the lenses. This part implements sections 520(g) and 520(l) of the act with respect to intraocular lenses.

(b) *Effect of exemption.* (1) In general, intraocular lenses are exempted from provisions of the following sections of the act and regulations thereunder when an application for exemption applicable to the lenses is in effect under this part: Misbranding under section 502, registration and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, records and reports under section 519, restricted devices under section 520(e), good manufacturing practices under section 520(f), and color additives under section 706.

(2) Intraocular lenses shall not be exempted from a provision of the act listed in paragraph (b)(1) of this section where the Commissioner indicates that the lens is not exempt from such a provision in an order of disapproval, approval, or approval with modifications under § 813.30.

§ 813.2 Applicability.

This part applies to all implantations of intraocular lenses in humans unless a premarket approval application has been approved for these lenses under section 515 of the act.

§ 813.3 Definitions.

(a) "Intraocular lens" means a lens intended to replace surgically the natural lens of the human eye. An intraocular lens is, for purposes of this part, synonymous with "investigational device," lens, or lenses.

(b) "Investigational device" means a device that is used in an investigational study involving human subjects, where the study is for the purpose of determining if the device is safe or effective.

(c) "Investigational plan" means a plan or protocol for using an investigational device in an investigational study. See § 813.25 for requirements applicable to an investigational plan.

(d) "Investigational study" means a study involving human subjects when the study is for the purpose of determining if an investigational device is safe or effective and includes any implantation in a human of an intraocular lens for which there is no approved application for premarket approval under section 515 of the act.

(e) "Investigator" means an individual who actually conducts an investigational study, i.e., under whose immediate direction the investigational device is administered or dispensed to, or used involving, a subject.

(f) "Monitor," when used as a noun, means an individual selected by a sponsor or contract research organization to oversee the progress of an investigational study. The monitor may be a full-time employee of a sponsor or contract research organization or a consultant to the sponsor or contract research organization. ("Monitor," when used as a verb, means the act of reviewing the progress of an investigational study.)

(g) "Sponsor" means a person who initiates an investigational study, but who does not actually conduct the study (i.e., the investigational device is administered or dispensed to, or used involving, a subject under the immediate direction of another individual). A person other than an individual, e.g., corporation or government agency, that uses one or more of its own employees to conduct an investigational study that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(h) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, an investigational study (i.e., under whose immediate direction the investigational device is administered or dispensed to, or used involving, a subject). The term does not include any person other than an individual. Any sponsor-investigator shall carry out the responsibilities under this part of a sponsor and of an investigator.

(i) "Institution" means a person (other than an individual) who engages in the conduct of research on human subjects or in the delivery of medical services to human

subjects as a primary activity or as an adjunct to providing residential or custodial care to human beings. The term includes a hospital, retirement home, prison, university, or device manufacturer. Facility as used in section 520(g) of the act is deemed to be synonymous with the term institution for purposes of this part.

(j) "Subject" means an individual who is or becomes a participant in an investigational study, either as a recipient of the investigational device or as a control. A subject may be either a non-patient volunteer or a patient on whom the intraocular lens might have a therapeutic effect.

(k) "Person" includes an individual, partnership, corporation, association, scientific establishment, government agency, and any other legal entity.

(l) "Institutional review committee" means a committee (appointed by an institution to review and monitor investigations in which human subjects participate) whose major responsibility is the protection of human subjects from risk to their health, safety, or dignity in accordance with the current professional standards and the requirements of this part. Such a committee may be known as an institutional review board or by other names.

§ 813.5 General qualifications for an exemption.

A shipment of an intraocular lens is exempt from any or all the otherwise applicable requirements of the act enumerated in § 813.1(b)(1) if all the following conditions are met:

(a) The label of the device bears the following: the name and place of business of the manufacturer, packer, or distributor in accordance with § 801.1 of this chapter; the quantity of contents; the sterility shelf life of the lens; and the statement, "Caution – investigational device. Limited by Federal (or United States) law to investigational use".

(b) The labeling of the intraocular lens is not false or misleading in any particular.

(c)(1) An application for investigational device exemption covering that shipment was submitted by the sponsor under Subpart B of this part, and the requisite time has elapsed following the date of receipt of the application by the Food and Drug Administration to permit the investigational study to begin under § 813.30(b).

(2) The Commissioner has not disapproved the application or withdrawn the exemption.

(3) Each shipment of the intraocular lens is made in accordance with the commitments in the application and any conditions imposed in the Commissioner's approval of the application.

(4) The sponsor has complied with the requirements of Subparts B, C, and G of this part, any institutional review committee that is to review and approve the investigational study for which shipment is made has complied with the requirements of Subparts D and G of this part, and the investigator(s) to which the shipment is to be made has complied with the requirements of Subparts E, F, and G of this part.

(d) If the shipment is to be imported into or exported from the United States, the requirements of § 813.19 have been met.

§ 813.10 Petitions for waiver of requirements.

(a) Any person subject to any requirement under this part may petition the Commissioner for a waiver of such requirement. Such a petition shall be submitted in accordance with § 10.30 of this chapter and shall set forth the basis for the petitioner's belief that compliance with the requirement is not necessary to achieve the objectives of this part and, where appropriate, any alternative means to achieve the objective of the requirement from which the waiver is sought.

(b) The Commissioner may, at his discretion grant a petition for a waiver submitted under this section if he finds that compliance with the requirement from which the waiver is sought is not necessary to achieve the objectives of this part and, where appropriate, that the proposed alternative means will achieve the objective of the requirement from which the waiver is sought.

(c) The person who submits a petition under this section continues to be subject to the requirement from which the waiver is sought unless and until the Commissioner grants the petition.

§ 813.12 Information previously submitted.

Wherever this part requires the submission to the Food and Drug Administration of information or data that previously had been submitted in accordance with

this part or other parts of this Chapter, the information or data need not be resubmitted but may be incorporated by reference.

§ 813.19 Requirements applicable to importers and exporters of intraocular lenses.

(a) Any person who imports or offers for importation into the United States an intraocular lens shall assure that all the following requirements are met:

(1) The labeling of such lens complies with § 813.5(a) and (b).

(2) The importer of such shipment is an agent in the United States of the foreign exporter or is the ultimate consignee, and the foreign exporter or the ultimate consignee has, prior to such shipment, completed and submitted to the Food and Drug Administration an application for an investigational device exemption in accordance with § 813.20 and acts as the sponsor of the investigational study to assure compliance with the procedures, conditions, and requirements of this part.

(3) The requisite time has elapsed after the date of receipt of the application by the Food and Drug Administration to permit the investigational study to begin under § 813.30(b).

(4) The Commissioner has not disapproved the application or withdrawn the exemption.

(b) Any person who exports an intraocular lens from the United States to a foreign country shall comply with all the following requirements:

(1) The lens shall conform to the specifications of the foreign purchaser.

(2) The lens shall comply with the laws of the country to which it is being exported.

(3) The label on the outside of the shipping package shall indicate that the lens is intended for export.

(4) The lens shall not be sold or offered for sale in domestic commerce.

(5) The person shall obtain the approval of the exportation of the lens from the country to which it is intended for export.

(6) The person shall request and obtain from the Commissioner a determination that the exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export.

Subpart B – Applications for Exemption for Investigational Studies Involving Human Subjects

§ 813.20 Application.

(a) The sponsor of an investigational study shall submit to the Food and Drug Administration a completed application for an investigational device exemption that has been signed by the sponsor or an authorized representative of the sponsor. Three copies of the application and any material required to accompany the application, bound and contained in volumes of reasonable size, shall be sent by registered mail or hand delivered to the Bureau of Medical Devices, Document Control Center (HFK-20), Food and Drug Administration, 8757 Georgia

Ave., Silver Spring, Md. 20910. Any subsequent reports, correspondence concerning an application, and supplemental application submitted under § 813.39 also shall be submitted in triplicate by registered mail or hand delivered to this address. The outside wrapper of any application or supplemental application should include the statement "Application (or Supplemental Application) for Investigational Device Exemption" and the outside wrapper of any reports or correspondence should include the statement, "Regarding an Investigational Device Exemption".

(b) An application for an investigational device exemption for an intraocular lens shall include the following information:

(1) A brief statement of its intended use(s) and how it is to be administered.

(2) A description of all components, ingredients, and properties and a description of the principle of operation of the device and any anticipated changes in the device that may occur in the course of the study, in enough detail so that a scientist or physician familiar with the general type of lens can make a knowledgeable judgment about the anticipated safety and effectiveness of the lens in the proposed investigational study.

(3) A description of those methods, facilities, and controls, used for the manufacture, processing, packing, and storage of the device in enough detail so that a person generally informed in that area can make a knowledgeable judgment about the safety and effectiveness of the device in the proposed investigational study.

(4) A statement of the location(s) of the study and whether an institutional review committee(s) is to monitor the study at such location(s).

(5) A report of prior investigations of the device that meets the requirements of § 813.27 and a summary of the investigational plan.

(6)(i) A statement from the sponsor that an investigational plan that meets the requirements of § 813.25 and a report of prior investigations of the device that meets the requirements of § 813.27 have been submitted to and approved by the institutional review committee, or (ii) if no institutional review committee exists and one cannot be formed, a statement from the head of the institution that such a committee cannot be formed, and copies of the investigational plan and the report of prior investigations.

(7) A statement from any institutional review committee (where a committee is to monitor the study), signed by the chairman, that the committee has approved the investigational plan and has reviewed the report of prior investigations of the lens, that the committee will review the study periodically at intervals appropriate to the degree of risk but not to exceed 1 year, and that it will review reports of unexpected adverse effects on a timely basis for the purpose of determining if the study should be continued.

(8) A copy of all informational materials to be given to subjects, including all form(s) to be used to obtain informed consent of human subjects as required by Subpart F of this part (this material may be appended to the

investigational plan or the summary of the investigational plan).

(9) A copy of all informational material, including labels and other labeling, which is to be supplied to investigators as required by § 813.47(a).

(10) A description of the scientific training and experience that the sponsor considers appropriate to qualify individuals as suitable experts to investigate the safety and effectiveness of the intraocular lens. (See § 813.43(a).)

(11) A copy of the agreement signed by investigators who will be participating, to comply with Subparts E, F, and G as required by § 813.43(b).

(12) The name and a summary of the training and experience of the individual who is to monitor the progress of the study for the sponsor as required by Subpart C.

(13) A statement as to whether any institutional review committee has ever disapproved any investigational study of the device and the reasons for such disapproval.

(14) A statement that the sponsor will comply with each of the requirements of Subparts C and G of this part.

(15) A statement by a sponsor notifying FDA if he intends to charge investigators and subjects for the device.

(16) A statement by the sponsor of his reasons for any request for a waiver of the requirement of § 813.30(a) that a study shall not begin before the expiration of 30

days after the Food and Drug Administration has received an application meeting the requirements of this subpart, if such waiver is requested.

(17) An environmental impact statement meeting the requirements of Part 25 of this chapter when requested by the Food and Drug Administration after receipt of an application under this section.

(18) Any other information relevant to review of the application required by the Food and Drug Administration to be submitted. The sponsor may refuse to provide the information requested under paragraph (b)(18) of this section and treat FDA's request as a final disapproval for purposes of requesting a regulatory hearing under § 813.30. If a sponsor fails to respond to a request for information within the time prescribed in a request, FDA may treat the application as withdrawn.

§ 813.25 Investigational plan.

(a) The investigational plan for the investigational study of an intraocular lens shall include the following:

(1) A statement of the intended use of the lens:

(2) A general outline of the plan and any anticipated or forseeable changes or variations in the plan that may be made based on experience gained in the study;

(3) A description of what results are expected from the investigational study;

(4) A justification for beginning the study, taking into account prior experience with the intraocular lens;

(5) The expected duration of the investigational study;

(6) Indentification of the investigator or investigators, the facilities where the study will occur, and any institutional review committees that will supervise the study;

(7) The patient population in which the lens will be used (in terms of age, sex, and condition) and the size of each population;

(8) A justification for using such patient population and of the size of each population;

(9) The sponsor's plan for monitoring the study in accordance with § 813.46;

(10) A description of records to be maintained, and the reports to be made by the investigator(s) and the sponsor to assure compliance with the plan and enable the progress of the investigation and the safety and effectiveness of the lenses to be reviewed by the sponsor, any institutional review committee, and the Food and Drug Administration;

(11) The plan for obtaining informed consent from subjects and copies of all informational materials to be given to subjects, including all forms and materials to be used in obtaining such consent; and

(12) A description of the scientific training and experience the sponsor considers appropriate to qualify individuals as suitable experts to investigate the safety and effectiveness of the intraocular lens. (See § 813.43(a).)

(b) The procedures and conditions in the investigational plan may vary depending on the following:

(1) The scope and duration of the investigational study;

(2) The number of human subjects who are to be involved in the study;

(3) The need to permit changes to be made in the device during the study conducted in accordance with the plan; and

(4) The purpose of the study, e.g., whether the study is designed for developing data to obtain approval for the commercial distribution of the device.

(c) When an investigational study is to develop data to obtain approval for commercial distribution of the device, the Food and Drug Administration will not ordinarily regard an investigational plan as capable of providing data that will support an application for such approval unless it provides for more than one independent qualified investigator.

(d) The investigational plan may provide for additional animal tests to be made during the investigational study.

§ 813.27 Report of prior experience with the lens.

(a) A report of prior investigations with the lens shall be submitted to an institutional review committee and to the Food and Drug Administration.

(b) The report of prior investigations of a lens shall include:

(1) A bibliography of any publications relevant to the investigational study and copies of significant publications both adverse and supporting.

(2) Any other unpublished information available to the sponsor, both adverse and supporting, information relating to preclinical investigations of the lens, including appropriate tests in animals and tests in vitro, and prior clinical investigations of the device or clinical experience with the device from commercial marketing, whether in the United States or in foreign countries, in sufficient detail so that a scientist or physician familiar with the general type of lens can make a knowledgeable judgment about the anticipated safety and effectiveness of the device in the proposed investigational study.

(c) Prior investigations of a lens shall not be considered adequate to justify an investigational study involving human subjects unless the conditions of the prior investigations of the lens are comparable to the conditions of the proposed investigational study.

§ 813.30 Food and Drug Administration review of and action on an application.

(a) Upon receipt of an application for an investigational device exemption submitted in accordance with this subpart, the Food and Drug Administration will notify the sponsor of the date of such receipt and inform the sponsor that the investigational study may not be begun until 30 days after the date of the agency's receipt of the application, unless the agency has decided to waive the 30-day time requirement and so informs the sponsor.

(b) An application for an investigational device exemption shall be deemed to be approved on the 30th day after the Food and Drug Administration received the application unless, on or before such day, the Commissioner finds that the application does not meet the requirements of this part and by order disapproves the application, stating his reasons therefor, or finds the application deficient and requests additional information or suggests revisions, or approves the application with modifications. If the Commissioner requests additional information or suggests revisions, the sponsor may treat the application as disapproved for purposes of requesting a regulatory hearing under Part 16 of this chapter.

(c) The Commissioner may by order disapprove an application if he makes any of the following findings:

(1) The application contains an untrue statement of a material fact or omits material information required by § 813.20.

(2) The report of prior investigation of the intraocular lens is inadequate to support a conclusion that it is reasonably safe to begin or continue the proposed investigational study.

(3) There is reason to believe that the lens may be unsafe or ineffective when used for the purpose or in the manner for which it is to be investigated.

(4) The investigational plan described in the application is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the investigational device is safe or effective.

(5) The methods, facilities, and controls used for the manufacturing, processing, packing, storage, or implantation of the lens do not assure adequately the safety and effectiveness of the lens.

(6) The sponsor's proposed use of the lens is not intended solely for an investigational study, since it is being or is to be sold or otherwise commercially distributed in a manner not justified by the requirements of the investigational study and not permitted by this part.

(7) The proposed investigational study on which the application is submitted does not conform to procedures, conditions, or requirements prescribed in this part.

(8) The proposed investigational study subjects human subjects to undue risks. In assessing risks, the Commissioner shall consider, among other things, the factors prescribed in § 813.66(f).

(d) The Commissioner shall notify the sponsor of an approval, disapproval, or approval with modifications of an application. The notification shall contain the order of the approval, disapproval, or approval with modifications and a complete statement of the reasons for the order. An order that is a notification of disapproval or approval with modifications shall advise the sponsor that he has recourse to an opportunity for a regulatory hearing pursuant to Part 16 of this chapter.

(e) The Commissioner may in his discretion decide not to disapprove an application for which there are grounds for disapproval if he concludes that risks do not outweigh the benefits to subjects.

§ 813.35 Withdrawal of an exemption.

(a) The Commissioner may by order withdraw an exemption granted under this part if he makes any of the following findings:

(1) The application for such exemption or any subsequent report contains an untrue statement of material fact or omits material information required by §§ 813.20, 813.39, or Subpart C of this part.

(2) The report of prior investigations of the device is inadequate to support a conclusion that it is reasonably safe to continue the investigational study involving human subjects.

(3) There is reason to believe that the investigational device may be unsafe or ineffective when used for the purposes or in the manner for which it is investigated.

(4) The investigational plan described in the application is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the investigational device is safe or effective.

(5) The methods, facilities, and controls used for the manufacturing, processing, packing, storage, or installation of the investigational device do not adequately assure its safety and effectiveness.

(6) The investigational study is not being conducted in accordance with the investigational plan submitted to the Food and Drug Administration or the institutional review committee; or any change in, or deviation from,

the investigational plan was not approved as required by § 813.39 and § 813.106.

(7) The sponsor's use of the investigational device is not solely for an investigational study since it is being or is to be sold or otherwise commercially distributed in a manner not justified by the requirements of the investigational study and not permitted by this part.

(8) The sponsor has failed to submit an application for premarket approval of the device when requested to do so by the Food and Drug Administration pursuant to § 813.46(d).

(9) The investigational study does not conform to procedures, conditions, or requirements prescribed under this part.

(10) The investigational study subjects human subjects to undue risks. In assessing risks, the Commissioner shall consider, among other things, the factors prescribed in § 813.66(f).

(11) The process of review or monitoring undertaken by the institutional review committee that is monitoring the study is inadequate.

(b) The Commissioner may in his discretion decide not to disapprove an application for which there are grounds for disapproved if he concludes that the risks do not outweigh the benefits to subjects.

(c) An order under this section shall include a complete statement of the reasons for the Commissioner's action. Such order shall be issued only after the sponsor has been afforded an opportunity for a regulatory hearing pursuant to Part 16 of this chapter, except that the

order may be issued before providing an opportunity for such hearing if the Commissioner determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health or safety.

(d) An exemption that has been withdrawn under this section may be reinstated if the sponsor satisfies the Commissioner that the grounds for withdrawal no longer apply.

§ 813.38 Confidentiality of data and information in an application.

(a) The existence of an application for an investigational device exemption will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in the Food and Drug Administration file concerning the application shall be handled in accordance with the provisions established in § 314.14 of this chapter for the confidentiality of data and information in new drug applications.

(c) Notwithstanding the provisions of § 314.14 of this chapter, the Food and Drug Administration shall disclose upon request to an individual in whom an intraocular lens has been used a copy of any adverse reaction report relating to such use.

§ 813.39 Supplemental applications and submissions concerning applications.

(a) Except as provided in paragraphs (b), (c), and (d) of this section, information contained in an application submitted under § 813.20 may be updated by means of a report to the Food and Drug Administration under § 813.153.

(b)(1) Whenever the sponsor or any investigator participating in an investigational study wishes to implement a change in, or deviation from, the investigational plan submitting to the Food and Drug Administration under § 813.20 that may affect the validity of the study or the rights or safety of the human subjects under the criteria in paragraph (b)(3) of this section, the sponsor shall submit to the Food and Drug Administration a supplemental application describing the proposed change or deviation and the justification therefore. Except as provided in paragraph (b)(2) of this section, the sponsor shall submit the supplemental application before the change or deviation is implemented, shall obtain the prior review and approval of any institutional review committee pursuant to §§ 813.42(d) and 813.105, shall attach to such supplemental application a copy of the approval of such change or deviation by such committee, and shall not permit the change or deviation to be implemented unless and until the supplemental application is approved or deemed approved under § 813.30(b), except as described in paragraph (b)(2) of this section.

(12) When a change or deviation is necessary to eliminate or reduce an apparent immediate hazard to the safety of a human subject who is already participating in

the investigational study, the sponsor is not required to comply with the prior approval requirements of paragraph (b)(1) of this section. The sponsor shall instead notify the Food and Drug Administration and any institutional review committee not notified by the investigator of the change or deviation and the justification therefor as soon as possible but in no event later than 5 days after he learns of such change or deviation.

(3) The following changes in, or deviations from, an investigational plan illustrate some of the situations in which prior review and approval are required under paragraph (a) of this section:

(i) A significant change in the method of administration or use of the lens.

(ii) A significant change in the number of subjects participating in the study at one time or cumulatively.

(iii) The use of subjects with medical conditions unrelated to, but possibly affecting, the scope or validity of the study.

(iv) The use of human subjects who require special consideration or protection and who are not listed specifically in the plan, e.g., children, mentally disabled individuals, or prisoners.

(v) The administration of concomitant or concurrent therapy where it is likely that an interaction with the lens might occur.

(c) The sponsor shall submit to the Food and Drug Administration the signed statements required under § 813.43(b) for any additional investigators and, as required by § 813.42(d), the statement signed by the

chairman of any institutional review committee that is added to an investigational study after submission of an application for an investigational device exemption under § 813.20(b). Any such additional statement shall be submitted before an investigator may begin participation in the investigational study.

(d) The sponsor shall submit to the Food and Drug Administration any additional informational materials to be given to subjects, including forms, or revisions in informational materials or forms, to be used by investigators to obtain informed consent of human subjects and any additional informational materials, or revision in such informational materials, supplied to investigators, which had not been submitted in an application under § 813.20(b), (8) and (9) or any subsequent reports to the Food and Drug Administration. The sponsor shall submit such forms or materials to the Food and Drug Administration at the same time that they are provided to investigators.

Subpart C – Sponsor Responsibilities in Investigational Studies of Intraocular Lenses

§ 813.40 General.

The requirements of this subpart are applicable to sponsors of investigational studies, including sponsor-investigators.

§ 813.43 Review of the Investigational study by the Food and Drug Administration and the institutional review committee.

(a) The sponsor shall submit for review and approval by the Food and Drug Administration an application for an investigational device exemption in accordance with Subpart B of this part before any human subjects are allowed to participate in the investigational study.

(b) The sponsor shall not permit any human subjects to participate in the study until the study has been approved by an institutional review committee and the application for exemption is approved by the Food and Drug Administration.

(c) The sponsor shall assure that the institutional review committee and the Food and Drug Administration are provided all the information on the proposed investigational study and the lens that they will need to review, approve, and monitor the study.

(d) The sponsor shall obtain from the institutional review committee a statement, signed by the chairman, that the committee has approved the investigational plan and has reviewed the report of prior investigations of the lens and that the committee will monitor the investigation in accordance with Subpart D of this part.

(e) The sponsor shall not implement a change in or deviate from the investigational plan, or permits a change or deviation to be implemented, unless there has been compliance with the requirements of §§ 813.36 and 813.106.

§ 813.43 Selection of Investigators.

(a) The sponsor shall select as investigators only individuals who, because of their training or experience, qualify as suitable experts to investigate the safety and effectiveness of the lens. As a minimum, investigators shall have completed successfully a residency in ophthalmology or its documented equivalent and be licensed to practice medicine in the State or country in which the investigational study is to take place. Sponsors shall adopt appropriate additional criteria for investigators (bearing in mind the investigational plan, the report of prior investigations of the lens, and what is known about the lens).

(b) The sponsor shall obtain from each investigator who will participate in the investigational study a signed agreement for submission to the Food and Drug Administration that includes the following:

(1) A statement of the investigator's education and experience in sufficient detail to allow determination of the investigator's qualifications for investigating the lens. Such statement shall include specific experience with the intraocular lens to be investigated, including date, amount and description of experience, and the name of the institutions where the lens was investigated or used.

(2) An agreement to comply with the investigational plan and the requirements of Subparts E, F, and G of this part.

(3) An agreement that any use of the lens involving human subjects will be under the investigator's supervision or under the supervision of another investigator who

is responsible to him and who is named by the investigator in a signed statement under paragraph (b)(5) of this section.

(4) A statement as to whether any investigational study or other research by such investigator has been discontinued on the order of a sponsor, an institutional review committee, or the Food and Drug Administration.

(5) The name of any other investigator who will participate in the investigational study, who is under the investigator's supervision and responsible to him, with a statement of such other investigator's education and experience in accordance with paragraph (b)(1) of this section.

§ 813.45 Control over the intraocular lens.

(a) The sponsor shall permit the lens to be shipped only to investigators who have signed statements under § 813.43(b).

(b) If the study is suspended, terminated, completed, discontinued, or the exemption is withdrawn, the sponsor shall require the investigator to dispose of the lens in accordance with the requirements of § 813.107(b).

(c) The sponsor shall assure that the methods, facilities, and controls selected for investigating and implanting the lens are adequate to assure the device will be tested under conditions that adequately assure the safety and effectiveness of the lens in the investigational study and, where the sponsor is a manufacturer, distributor or importer of the lens, he shall also assure that the methods, facilities, and controls used for the manufacture, processing, and storage of the lens adequately

assure the safety and effectiveness of the lens in the investigational study.

§ 813.46 Monitoring the investigational study.

(a) The sponsor shall designate one or more appropriately trained and qualified individuals to monitor the progress of the investigational study on a continuing basis and evaluate the data concerning the safety and effectiveness of the lens on behalf of the sponsor upon receipt of such data from investigators, and shall assure that such monitoring and evaluation occur.

(b) The sponsor shall review the investigational study periodically at intervals appropriate to the degree of risk to assure that the requirements of this part are met.

(c) Upon discovery by the sponsor that the investigator has not complied with the requirements of this subpart and Subpart G of this part or his agreement under § 813.43(b), the sponsor shall secure the investigator's compliance or discontinue shipments to the investigator and may require the investigator to return or otherwise make appropriate disposition of the lens in accordance with the requirements of § 813.107(b), and may suspend or terminate any study being performed by the investigator for the sponsor.

(d) A sponsor shall not unduly prolong an investigational study. Where data are developed in the study that would support submission of an application for premarket approval of the lens pursuant to section 515 of the

act, the sponsor shall either submit such an application or discontinue the study.

(e) Where the sponsor learns from an investigation and report of an adverse reaction under § 813.153(b) that a serious adverse reaction is lens related and presents unreasonable risk to subjects involved in the study, he shall discontinue the study as soon as possible but in no event later than 5 days after sufficient information is available to warrant suspension. For purposes of this section, suspension of the investigational study means that no new subjects may be added to the study. Where the Food and Drug Administration regards an adverse reaction as lens related and as presenting unreasonable risk to subjects, the agency may request or order the sponsor to suspend the study and to take appropriate action to protect subjects in whom lenses have been implanted. The sponsor shall suspend the study and take such other action as soon as possible but in no event later than 5 days after such request or order. Once the study has been suspended, the sponsor shall not resume the study without the concurrence of the Food and Drug Administration.

§ 813.47 Submitting information to investigators.

(a) The sponsor shall supply all investigators with copies of the investigational plan required under § 813.25, the report of prior investigations of the lens required under § 813.27, and labeling (including labels) for the lens that describes all relevant hazards, contraindications, adverse reactions, interfering substances, precautions suggested by prior investigations, the sterility shelf life of

the lens, and experience with the lens. The labeling shall not represent that the safety or effectiveness of the lens has been established for the purposes to be investigated.

(b) The sponsor shall notify each investigator of the completion or discontinuance of the investigational study or the withdrawal of the exemption as soon as possible but in no event later than 5 days after such action.

(c) The sponsor shall notify each investigator if an application for premarket approval of the device under section 515 of the act is approved.

§ 813.50 Promotion and sale of intraocular lenses.

(a) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the lens being investigated is safe and effective for the purposes for which it is under investigation. This requirement does not restrict the full exchange of scientific information concerning the device, including dissemination of scientific findings. However, this requirement prohibits promotional claims by the sponsor that the lens is safe and effective while the device is being investigated to establish its safety and effectiveness.

(b) The sponsor of the study of an intraocular lens may distribute the lens only if the sponsor has an effective exemption under this part for all lenses sold, and all patients who receive a lens are included in an investigational study under an exemption.

Subpart D – Institutional Review Committee

§ 813.60 Requirement of institutional review committee.

An institutional review committee shall review and monitor all investigational studies of an intraocular lens, except that where an institutional review committee does not exist and one cannot be established, the sponsor of the study shall submit the investigational plan and report of prior investigations pursuant to § 813.20(b) (5) and (6) for review by the Food and Drug Administration. The Food and Drug Administration may disapprove a study that is not to be reviewed and monitored by an institutional review committee if, in the opinion of the Commissioner, the lack of institutional review committee review may expose human subjects to undue risk.

§ 813.62 Membership of an institutional review committee.

(a) Any institutional review committee that undertakes to participate in the review of a proposed study shall possess the professional competence necessary to review the specific study. An institutional review committee shall be composed of not less than five individuals with varying backgrounds to assure complete and adequate review of the investigational study. Such committee shall include, in addition to persons possessing the professional competence necessary to review scientific activities, persons whose primary concerns are in nonscientific areas, e.g., lawyers, clergymen, ethicists, social scientists, or other lay persons. No such committee shall consist entirely of members of a single professional group.

(b) The records of a committee shall identify each member by name, earned degrees, positions or occupation, representative capacity, and other pertinent indications of experience, such as board certification or licenses, sufficient to describe each member's chief anticipated contributions to such committee's deliberations. The employment or other relationship between each member and the institution and any investigator or sponsor of any investigational study reviewed and monitored by the committee shall be described in the records of the committee, e.g., full-time employee, part-time employee, member of governing panel or board, paid consultant, or unpaid consultant.

(c) No committee shall consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the committee.

(d) No member of a committee shall participate in the committee's review of monitoring of an investigational study in which he has a conflicting interest. No investigator or sponsor shall participate in the selection of members for a committee that will review his investigational study.

(e) The committee is responsible for determining whether a member has a conflict of interest and, if so, such member shall not participate in the review or monitoring of the study.

(f) An institutional review committee may in its discretion invite persons with competence in particular areas (consultants) to assist in the review of complex issues whose resolution requires expertise beyond or in

addition to that available within the committee. Consultants may not vote.

§ 813.65 Procedures for review and monitoring of investigational studies by an institutional review committee.

(a) An institutional review committee shall follow written procedures adopted by either the committee or the institution for conducting its review and monitoring of investigational studies and for reporting its findings to the institution, the sponsor, and the investigator.

(b) A committee shall conduct business by a quorum, which shall be defined by written procedures. In no event shall a quorum be less than a majority of the members of the committee.

(c) A committee participating in the review of an investigational study shall monitor that study until the investigation is completed or discontinued by the sponsor or terminated or suspended by the committee or an exemption is withdrawn by the Food and Drug Administration.

§ 813.66 Procedures and criteria for review of investigational studies by an institutional review committee.

(a) Upon receipt of the proposed investigational study, including an investigational plan and a report of prior investigations of the lens from the sponsor or investigator, a committee that is to participate in the review of the study shall perform the following functions:

(1) Determine that each investigator has successfully completed a residency in ophthalmology or its documented equivalent, and is licensed to practice medicine in the State or country in which the investigational study is to take place.

(2) Review the investigational plan and determine that the nature of the investigational study provides a benefit to the proposed subjects such that the risks to the subjects are justified.

(3) Assure that sufficient records will be kept so as to describe clearly the results of the study.

(4) Require the investigator to notify the institutional review committee of any unanticipated side effects or increased hazards or any changes in the investigational study, actual or proposed, that have resulted or may result from the preliminary findings of the study that could result in modification or reversal of the initial determination to authorize beginning the study.

(5) Monitor the investigational study at intervals appropriate to the degree of risk but in no event exceeding 1 year so as to assure that the study continues to be justified during the course of the study.

(6) Assure that the rights of human subjects are properly protected, that legally effective informed consent is obtained, and that the method of obtaining consent properly informs the human subject of the significant aspects of the study in accordance with Subpart F of this part.

(7) Receive, process, and act on complaints relating to any study under review, e.g., from subjects, sponsors, and other members of an institution's staff.

(b) If the committee has any question regarding the proposed investigational study, the committee may request the investigator or sponsor to submit additional information concerning the proposed study.

(c) The committee shall review and approve, approve with modifications, or disapprove a proposed study as soon as possible after receipt thereof.

(d) The committee may disapprove a proposed study for any reason it considers appropriate and shall disapprove a proposed study if it makes any of the following findings:

(1) The information submitted to the committee concerning the study contains an untrue statement of a material fact or omits material information required by this part.

(2) The report of prior investigations of the lens is inadequate to support a conclusion that it is reasonably safe to begin the proposed investigational study.

(3) There is reason to believe that the lens may be unsafe or ineffective when used for the purpose or in the manner for which it is to be investigated.

(4) The investigational plan is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the lens is safe or effective.

(5) The proposed investigational study does not conform to procedures, conditions, or requirements prescribed in this part.

(6) The investigator does not possess the scientific training and experience appropriate to qualify him as a suitable expert to investigate the safety and, where appropriate, effectiveness of the lens.

(7) The available clinical laboratory facilities and medical support are inadequate to assure that the study will be conducted properly and in conformity with the plan or to assure the safety of the subjects.

(e) A committee participating in the review may suspend or terminate a study after it has begun for any of the following reasons:

(1) Any reason for which the committee shall disapprove a study under paragraph (d) or (f) of this section.

(2) The investigator has disregarded committee recommendations for patient protection or has refused to cooperate with the committee, or to provide information to the committee.

(3) Experience developed during the study, or newly discovered scientific evidence not considered at the time the study was initially approved, indicates that the risks outweigh the potential benefit to the subjects.

(4) The investigator(s) who initiated the study cannot or will not continue to perform as an investigator, and a suitable qualified replacement is not available.

(5) There is evidence of fraud in the submission of data.

(6) The institutional support available for the study is no longer sufficient in quality or amount to assure the safe continuation of the study.

(7) There has been unethical conduct on the part of the investigator in the course of the study.

(8) Such other reasons as the committee may find appropriate.

In the event the committee terminates or suspends a study, it shall notify the sponsor and the Food and Drug Administration as expeditiously as possible, stating its reasons for the suspension the duration of the suspension, the conditions, if any, under which the study will be permitted to continue, and its recommendations for the proper care of subjects.

(f) The committee shall disapprove a proposed study as being inadequate to justify commencement of testing involveing [sic] human subjects if it determines that the proposed investigational study exposes the subjects to undue risks. In assessing risks, the committee shall consider, among other things, whether:

(1) The risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;

(2) The rights, safety, and welfare of any such subjects will be adequately protected;

(3) A legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part; and

(4) The conduct of the activity will be reviewed at timely intervals by the institutional review committee and the sponsor.

(g) The committee shall notify the sponsor or investigator who submitted the proposal of its decision on the proposed study. Notification of approval with modifications or of disapproval shall contain a statement of the reasons for the committee's approval with modifications or disapproval.

§ 813.70 Review by institution.

Approval, including approval with modifications, by an institutional review committee may be subject to further appropriate review and approval or rejection by institutional officials, but disapproval by the committee may not be overruled by such officials.

§ 813.79 Actions where review by an institutional review committee is inadequate.

(a) The Commissioner may determine that the process of review undertaken by an institutional review committee is inadequate if he finds that it failed to meet the requirements of this subpart or Subpart G of this part.

(b) If the Commissioner finds that the process of review or monitoring undertaken by the committee is inadequate, he may:

(1) Request the committee to change its process of review or monitoring to meet the requirements of this subpart and Subpart G of this part;

(2) Require the sponsor to obtain review or monitoring by a committee whose process of review or monitoring meets such requirements;

(3) Require that the application be reviewed by the Food and Drug Administration; or

(4) Disapprove the application for an investigational device exemption or withdraw the exemption.

Subpart E – Investigator Responsibilities in Investigational Studies of Intraocular Lenses

§ 813.100 General.

The requirements of this subpart are applicable to investigators of investigational studies, including sponsor-investigators.

§ 813.101 Review of investigational study by the Food and Drug Administration.

An investigator shall not allow human subjects to participate in an investigational study until such time as the investigational device exemption has been obtained from the Food and Drug Administration pursuant to Subpart B of this part.

§ 813.103 Review of investigational study by institutional review committee.

Where the investigation of an intraocular lens is subject to an institutional review requirement under § 813.60:

(a) An investigator shall not allow human subjects to participate in an investigational study until the committee has approved the study.

(b) An investigator shall not implement a change in, or deviate from, the investigational plan until he has complied with the requirements of § 813.105.

(c) An investigator shall report to the committee and to the sponsor any serious adverse reaction occurring in the study that may reasonably be regarded as lens related and that was not previously expected in nature or severity or degree of incidence in the investigational plan.

(d) An investigator shall notify the committee within 3 months after completion or discontinuance of, or the withdrawal of the exemption for, the entire investigational study or of his portion of the study, whichever occurs first.

(e) An investigator shall provide accurate and adequate information regarding the investigational study to the committee in response to its request.

§ 813.105 Conformity to investigational plan.

(a) Whenever the investigator desires to implement a change in the investigational study that will result in a deviation from the investigational plan, he shall:

(1) Where such change may reasonably be expected to increase the risks to subjects and/or affect the scientific validity of the study under the criteria in § 813.39(b), notify the sponsor of the proposed change and obtain the

sponsor's assent; submit, or assure that the sponsor submits, to the investigational review committee notice of such change and obtain the written approval of the investigational review committee; and submit, or assure that the sponsor submits, to the Food and Drug Administration a supplemental application in accordance with § 813.39(b) and obtain the approval of the Food and Drug Administration before implementing the proposed change.

(2) Where such change may not reasonably be expected to increase the risks to the subjects, and does not affect the scientific validity of the study involved, the investigator may implement the change, but shall notify the sponsor and the institutional review committee involved. The notice of the change shall be reflected in sponsor, investigator, and institutional review committee records and in reports under § 813.153(c) and shall be reviewed by the institutional review committee in the regular course of business.

(b) When a change in or deviation from the investigational plan is necessary to eliminate or reduce an apparent immediate hazard to the safety of a human subject who is already participating in the investigational study, the investigator is not required to comply with the prior approval requirements of paragraph (a) of this section. The investigator shall instead notify any institutional review committee and the sponsor, who shall notify the Food and Drug Administration of the change or deviation and the justification therefor as soon as possible but in no event later than 5 days after such change or deviation is implemented as required by § 813.39(b)(2).

§ 813.107 Control over intraocular lenses.

(a) An investigator shall only permit the lens to be used for administration to, or use involving, subjects who are under his personal supervision or under the supervision of another investigator who is responsible to him and who is named by the investigator in his signed statement undertaking the obligations of an investigator under § 813.43(b). An investigator shall not supply the lens to any other person for administration to, or use involving, subjects or for any other purpose, without the prior authorization of the sponsor.

(b) An investigator shall return to the sponsor any reusable or unused supply of the lens upon direction of the sponsor, or upon suspension, termination, completion, discontinuance of, or withdrawal of the exemption for, the investigational study. The sponsor may direct or agree to alternative disposition of the lens such as destruction or use in animal or in vitro experiments.

§ 813.119 Disqualification of a clinical investigator.

(a) *Purposes.* The purpose(s) of disqualification of an investigator who has violated the regulations set forth in this part may be one or both of the following:

(1) To preclude the investigator from conducting clinical investigations subject to requirements under the act for prior submission to the Food and Drug Administration until such time as it becomes likely that he will abide by such regulations or that such violations will not recur. The determination to disqualify an investigator

does not necessarily constitute a finding or recommendation that the investigator is not qualified to practice or teach medicine or should be subject to other sanctions by other persons such as licensing boards or employers.

(2) To exclude the consideration of any clinical investigations or portions thereof in support of applications for an investigational exemption or for premarket approval from the Food and Drug Administration, which investigations have been conducted in whole or in part by the investigator, until such time as it becomes likely that he will abide by such regulations or that such violations will not recur or that it can be adequately demonstrated that such violations did not occur during or affect the validity or acceptability of a particular investigation or investigations. The determination that a clinical investigation may not be considered in support of an application for exemption or premarket approval does not, however, relieve the applicant for such an application of any obligation under any other applicable regulation to submit the results of the investigation to the Food and Drug Administration.

(b) *Grounds for disqualification.* The Commissioner may disqualify an investigator upon finding all the following:

(1) The investigator violated any of the regulations set forth in this part;

(2) The violation or violations adversely affected the validity of the clinical investigation, the rights of the human subjects, and/or the safety of the subjects; and

(3) Other lesser regulatory actions, e.g., warnings or rejection of data from individual investigations, have not been or will probably not be adequate to assure that the investigator will comply with such regulations in the future.

(c) *Notice of and opportunity for a hearing on proposed disqualification.* (1) Whenever the Commissioner has information indicating that grounds exist under paragraph (b) of this section that in his opinion may justify disqualification of an investigator, he may issue to the investigator a written notice proposing that the investigator be disqualified.

(2) A hearing on the disqualification of an investigator shall be conducted in accordance with the requirements for a regulatory hearing set forth in Part 16 of this chapter.

(d) *Final order on disqualification.* (1) If the Commissioner, after the regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the findings required in paragraph (b) of this section, he shall issue a final order disqualifying the investigator. Such order shall include a statement of the basis for that determination and shall prescribe any actions (set forth in paragraph (e) of this section) to be taken with regard to ongoing regulated clinical investigations being conducted by the investigator. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the investigator of the action, as well as the sponsor of each clinical investigation subject to requirements for prior submission to the

Food and Drug Administration that was being conducted by the investigator and has not been terminated or discontinued or the exemption under which it is being conducted has not been terminated or withdrawn by the Food and Drug Administration.

(2) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, does not make the findings required in paragraph (b) of this section, he shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify the investigator and provide a copy of the order.

(e) *Actions upon disqualification.* (1) No clinical investigations subject to requirements for prior submission to the Food and Drug Administration will be authorized by the Food and Drug Administration if such investigation is to be conducted, in whole or part, by a disqualified investigator.

(2) The Commissioner, after considering the nature of each ongoing clinical investigation that is being performed by the investigator and is subject to requirements for prior submission to the Food and Drug Administration, the number of subjects involved, the risks to them from suspension of the investigation, and the need for involvement of an acceptable investigator, may direct, in the final order disqualifying an investigator under paragraph (c)(1) of this section, that one or more of the

following actions be taken with regard to each such investigation:

(i) The investigation may be terminated or suspended in its entirety until the investigator is reinstated under paragraph (k) of this section or another investigator accepts responsibility for the investigation.

(ii) No new subject shall be allowed to participate, or be requested to participate, in the investigation until the investigator is reinstated under paragraph (k) of this section, or another investigator accepts responsibility for the investigation.

(iii) Any human subject who has previously been allowed to participate in the investigation and who remains under the supervision of the investigator should continue to be monitored by the investigator, but the human subject shall not receive another lens until the investigator is reinstated under paragraph (k) of this section or another investigator accepts responsibility for the investigational study.

(iv) Any human subject who has been allowed to participate in the investigation and who, except for suspension of the investigation, would have received the lens shall not receive it unless another investigator accepts responsibility for the investigation.

(f) *Disqualified investigators and applications.* Once an investigator has been disqualified, each application for an investigational exemption or for premarket approval, whether approved or not, containing or relying upon any clinical investigation performed by the investigator may be examined to determine whether the investigation was

or would be essential to a regulatory decision regarding the application. If it is determined that the investigation was or would be essential, the Food and Drug Administration shall also determine whether the investigation is acceptable, notwithstanding the disqualification of the investigator. Any investigation done by an investigator before or after disqualification may be presumed to be unacceptable, and the person relying on the investigation may be required to establish that the investigation was not affected by the circumstances that led to disqualification of the investigator, e.g., by submitting validating information. If the investigation is determined to be unacceptable, such investigation will be eliminated from consideration in support of the application, and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(g) *Clinical investigations begun by a disqualified investigator.* No clinical investigation begun by an investigator after the date of his disqualification will be considered in support of any application for an exemption or premarket approval application unless the investigator has been reinstated under paragraph (k) of this section. The determination that a clinical investigation may not be considered in support of an application for an exemption or premarket approval application does not, however, relieve the applicant of any obligation under any other applicable regulation to submit the results of the investigation to the Food and Drug Administration.

(h) *Public disclosure of information regarding disqualification.* (1) Upon issuance of a final order disqualifying an investigator, the Commissioner may notify any other person known to have professional relations with the

investigator (e.g., other Federal government departments or agencies that support investigations possibly involving the investigator, State and local medical licensing boards and societies where the investigator practices or is licensed, and administrators and institutional or peer review boards in universities, hospitals, and other institutions in which the investigator teaches or practices) that the investigator has been disqualified by the Food and Drug Administration. Such notice may be given in the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under paragraph (d) of this section and shall state that the disqualification constitutes a determination by the Food and Drug Administration that the investigator is not eligible to conduct clinical investigations subject to requirements for prior submission to the Food and Drug Administration and that the results of any clinical investigations conducted by the investigator may not be considered by the Food and Drug Administration in support of any application for an exemption or premarket approval application. The notice shall further state that it is given because of the professional relations between the investigator and the person notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(2) A determination that an investigator has been disqualified and the administrative record regarding such determination are disclosable to the public under Part 20 of this chapter.

(3) Whenever the Commissioner has reason to believe that an investigator may be subject to disqualification, he may, in his discretion, so notify the sponsor of any ongoing clinical investigation in which that investigator is participating simultaneously with or subsequent to proposing disqualification of the investigator under paragraph (c) of this section, unless there are overriding safety considerations that warrant earlier notification of the sponsor.

(i) *Alternative or additional actions to disqualification.* Disqualification of an investigator under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action in addition to or in lieu of (and prior to, simultaneously with, or subsequent to) disqualification. The Food and Drug Administration may also refer pertinent matters to another Federal, State, or local law enforcement or regulatory agency for such action as that agency deems appropriate.

(j) *Suspension or termination of an investigator by a sponsor.* The sponsor of an investigational study may at any time remove an investigator from further participation in the study, whether or not the Food and Drug Administration has begun any action to disqualify the investigator. The sponsor need not use either the grounds or the procedures for disqualification set forth in this subpart. If a sponsor removes an investigator from a study, the sponsor shall notify the Food and Drug Administration in writing of the reasons for such removal

as soon as possible, but in no event later than 5 days after such removal.

(k) *Reinstatement of a disqualified investigator.* An investigator who has been disqualified may be reinstated as eligible to conduct clinical investigations subject to requirements for prior submission to the Food and Drug Administration, or as acceptable to be the source of clinical investigations to be submitted to the Food and Drug Administration, if the Commissioner determines, upon an evaluation of a written submission from the investigator, that the investigator can adequately assure that he will conduct such studies in compliance with the requirements set forth in this part. A disqualified investigator who wishes to be so reinstated, shall present in writing to the Commissioner reasons why he believes he should be reinstated; the investigator shall also submit a detailed description of the corrective actions he has taken or intends to take to assure that the acts or omissions that led to disqualification will not recur. The Commissioner may condition reinstatement upon the submission of an acceptable protocol for a specific clinical investigation providing for additional corrective actions and/or the submission of special undertakings by a sponsor, an institution, an institutional review committee, or another investigator to review in detail the investigator's compliance with the requirements of this part and/or the investigator's being found in compliance with the applicable regulations upon an inspection. If an investigator is reinstated, the Commissioner shall so notify the investigator and all organizations and all persons who were notified under paragraph (h) of this section of the disqualification of the investigator. A determination that an investigator

has been reinstated is disclosable to the public under Part 20 of this chapter.

Subpart F – Informed Consent of Human Subjects

§ 813.120 General requirements of informed consent.

(a) The investigator shall (1) inform each human subject, or the subject's legal representative where the subject lacks legal capacity, that the intraocular lens is being investigated for safety and effectiveness, (2) provide each human subject, or his legal representative an adequate explanation of pertinent information concerning the lens, including the information required in § 813.130, and (3) obtain and document legally effective informed consent of such subject, or his legal representative.

(b) Informed consent shall be obtained while the subject, or his legal representative, is so situated as to be able to exercise free power of choice without undue inducement or the intervention of any element of force, fraud, deceit, duress, or other forms of constraint or coercion.

(c) Informed consent shall be evidenced by a written agreement, signed by the subject or his legal representative.

§ 813.130 Elements of informed consent in agreement.

(a) The investigator shall assure that the subject or his legal representative signs an agreement that includes a complete explanation of pertinent information concerning the lens, adequate to enable him to make a decision

on his willingness to participate or permit the subject to participate in the investigation, and which includes:

(1) A full and fair explanation of procedures to be followed, including an identification of any which are experimental.

(2) A full explanation of the nature, expected duration, and purpose of the administration of the lens.

(3) A description of any attendant discomforts and risks reasonably to be expected.

(4) An explanation of likely results should the procedure fail.

(5) A description of any benefits reasonably to be expected.

(6) A disclosure of any appropriate alternative procedures that might be advantageous for the subject, i.e., spectacles or contact lenses.

(7) A description of the scope of the investigation, including the number of patients involved in the investigational study.

(8) An offer to answer any inquiries concerning the investigational study.

(9) An instruction that the subject, or his legal representative, is free to decline entrance into the investigational study or to withdraw his consent and to discontinue participation in the study at any time without prejudice to the subject.

(10) A statement that the investigational lens is being used for research purposes.

(b) The agreement entered into by such person or his legal representative shall include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights or to release the institution or its agents, or the sponsor or the investigator from liability for negligence.

(c) An investigator shall provide to the sponsor and to any institutional review committee a sample copy of any written materials given or read to the subject or his legal representative, including the information required to be given by paragraph (a) of this section and a sample copy of any form used to document the consent of such subject or his legal representative, and the form shall have been approved by the committee.

Subpart G – Inspections, Reports, and Records

§ 813.150 Inspections.

(a) Any sponsor, institutional review committee, or investigator shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, to inspect and copy any records concerning the investigational study that are required to be kept by this part.

(b) Any sponsor or investigator who has authority to grant access to the facility shall also permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect any facilities where the intraocular lens is manufactured, processed, held, used, or implanted.

(c) Any investigator shall permit an authorized employee of the Food and Drug Administration to copy records that identify the names of human subjects, upon notice that the Food and Drug Administration has reason to believe that the consent of human subjects was not obtained, that reports submitted by the investigator to the sponsor or to the institutional review committee do not represent actual cases or actual results obtained, or that such reports or other required records appear to be otherwise false or misleading.

§ 813.153 Reports.

(a) *Recall reports.* Any sponsor shall notify the Food and Drug Administration of any request that investigators return, or otherwise dispose of, any supplies of the intraocular lens, or examine any patients that previously received a lens.

(b) *Adverse reaction reports.* If during the study a serious adverse reaction occurs that may reasonably be regarded as lens related and that was not previously expected in nature, severity, or degree of incidence in the investigational plan (including any incidence of hypopyon, intraocular infection, or acute corneal decompensation), the following actions shall be effected:

(1) The investigator shall investigate the reaction and submit an accurate and adequate report of the investigation to the sponsor and to the committee as soon as possible but in no event later than 5 days after learning of the reaction;

(2) The sponsor shall evaluate any adverse reaction report submitted by the investigator and any reports received from other sources and within 5 days after learning of the adverse reaction, shall report the adverse reaction and the results of his evaluation to the Food and Drug Administration, any committee(s) (a) monitoring the study, or part of the study, in which the reaction occurred (if the investigator(s) has not already reported the reaction to the committee(s)), and all other investigators and sponsors participating in the study. In the case of hypopyon, except where the Food and Drug Administration directs otherwise, a sponsor need only report the adverse reaction and results of his evaluation to other investigators and committees participating in the study where the incidence of the reaction exceeds that which was previously anticipated in materials provided to investigators.

(c) *Progress reports.* (1) Any investigator shall submit accurate progress reports to the investigational review committee and sponsor (or his monitor) at appropriate intervals but in no event at intervals exceeding 1 year.

(2) The sponsor shall make accurate and adequate progress reports to the Food and Drug Administration at appropriate intervals not exceeding 1 year. Such reports shall include any significant findings of the study and any necessary amendments or corrections to previous reports or to the application to keep them accurate.

(d) *Suspension/termination reports.* (1) Any investigator shall report to the sponsor any suspension or termination of the investigational study by a committee within 5 days.

(2) Any institutional review committee shall immediately report any suspension or termination of a study it is reviewing and monitoring under this part to the Food and Drug Administration.

(e) *Final reports.* (1) Within 3 months after the completion or discontinuance of or withdrawal of the exemption for the investigational study (or the investigator's portion of the study), any investigator shall notify the committee and sponsor and make an accurate and adequate final report to the sponsor, and the final report shall include all reports not previously submitted to the sponsor but required by paragraphs (b), (c), or (d) of this section.

(2) Within 30 days after the completion or discontinuance of a study or the suspension or termination of a study by a committee, the sponsor shall notify the Food and Drug Administration of the action.

(3) Within 6 months after the study is completed, discontinued, suspended, or terminated or the exemption is withdrawn, the sponsor shall make a final report to the Food and Drug Administration.

§ 813.155 Records.

(a) The sponsor, any investigator, and any committee shall maintain adequate and accurate records concerning the investigational study, including copies of all correspondence, among themselves and with the Food and Drug Administration regarding the study.

(b)(1) The sponsor and any investigator shall maintain adequate and accurate records showing the shipment, receipt, or other disposition of all supplies of all lenses shipped or received.

(2) The sponsor either shall provide to each investigator an identification card that is to be provided to each subject after implantation or shall provide each subject with such a card. The card shall include the following information on each lens: lens name, manufacturer's name and address, model number, style and serial, batch, lot, or other identification number for each lens. The sponsor and each investigator shall maintain the following records: identification by name of the investigator who received each unit of the lens and who administered the device; the identification by code of the subject who received it; and identification of each unit otherwise disposed of (including identification of the person who disposed of it, the person, if any, who received it, and the purpose or reason for its disposal, e.g., because of contamination or return to the sponsor).

(c) An institutonal review committee shall prepare and maintain adequate documentation of its activities regarding each investigational study, including records of information submitted to the committee by sponsors or investigators, information compiled on committee members pursuant to § 8.3.62, minutes of committee meetings on issues involved in the study and their resolution, committee decisions on the study, and dated deports of successive monitoring as it is performed.

(d) Contents of investigator records. An investigator shall maintain an adequate and accurate case report on each subject, which shall include the following:

(1) All relevant observations, information, and data on the condition of the subject at the time the subject enters into the study, including information regarding any relevant previous medical history and the results of all diagnostic tests performed to determine that the subject is appropriate for entry into the study.

(2) All documentation regarding the consent of the human subject, as required under Subpart F of this part.

(3) All relevant observations and data on the condition of the subject throughout the duration of his participation in the study.

(e) The sponsor shall retain a copy of any application, report, or correspondence that he submits to the Food and Drug Administration under this part.

(f) A sponsor, investigator, and institutional review committee shall maintain the records required under this part for whichever of the following periods is shortest:

(1) A period of 2 years after the date on which the Food and Drug Administration approves the marketing of the lens for the purposes that were the subject of the study.

(2) A period of 5 years after the date on which the results of the study are submitted to the Food and Drug Administration in support of the marketing of the lens for the purpose that was the subject of the study.

(3) In other situations, e.g., where the investigational study does not result in the submission of an application for marketing the device for the purposes that were the subject of the study, a period of 2 years after the date on which the investigational study (not merely an investigator's portion of a study) is terminated, completed or discontinued, or the exemption is withdrawn.

(g) A sponsor, investigator, or committee may withdraw from the responsibility for maintaining records for the period of time required in paragraph (f) of this section by transferring custody to any other person who will accept responsibility for the records. Notice of such transfer shall be given to the Food and Drug Administration.

(h) The Food and Drug Administration may require a sponsor to submit any records concerning the investigational study, including any records required to be kept under this part.

Subpart H – Investigational Studies That Do Not Involve Human Subjects

§ 813.160 Conditions of exemption.

(a) Where an investigational device is intended for use in humans, a shipment of the device that is intended solely for tests in animals used only for laboratory research purposes, or for in vitro or mechanical tests or similar tests that do not involve use of human subjects, shall be exempt from any of the otherwise applicable provisions of the act listed in § 813.1(c) if:

(1) The labeling of the device complies with the requirements of § 813.5(a) and (b) and bears the following additional statements:

CAUTION – DEVICE FOR INVESTIGATIONAL USE ONLY IN LABORATORY ANIMALS OR OTHER TESTS THAT DO NOT INVOLVE HUMAN SUBJECTS

(2) The person who ships the device under this subpart uses due diligence to assure that the consignee is regularly engaged in conducting tests in animals used only for laboratory research, or for in vitro or other mechanical tests or similar tests that do not involve use of human subjects and that the shipment of the investigational device will actually be used only in such tests.

(3) The person who ships the device under this subpart maintains adequate records showing the name and address of the consignee to whom the device is shipped, date, quantity, and batch or code mark of each shipment for a period of 2 years after such shipment and, upon the request of a properly authorized employee of the Department at reasonable times, makes such records available for inspection and copying or submits such records to the Food and Drug Administration.

(b) This subpart does not apply to any use of an investigational device that involves use of human subjects.

§ 813.170 Termination of exemption.

(a) The commissioner shall terminate an exemption under this subpart if he makes either of the following findings:

(1) The person shipping an investigational device under this subpart has failed to comply with any of the conditions for the exemption under this subpart.

(2) Any of the grounds for withdrawal of an investigational device exemption under § 813.35 apply.

(b) The Commissioner shall notify the sponsor of the termination of an exemption under this subpart with a full statement of the reasons for such termination and shall afford an opportunity for a regulatory hearing under Part 16 of this chapter. The person whose exemption is terminated shall recall or otherwise assure the destruction of any unused devices.

Effective date: This regulation shall become effective February 9, 1978.

([Secs. 301, 601, 602, 620, 701, 704, 801, 52 Stat. 1042-1043 as amended, 1048-1051 as amended, 1065, 90 Stat., 567, 568-571, 576-578 (21 U.S.C. 331, 361, 363, 380j, 371, 374, 381).)

21 C.F.R. § 886.3600

§ 886.3600 Intraocular lens.

(a) *Identification.* An intraocular lens is a device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.